VOLUME 15 NUMBER 5

Food-Drug-Cosmetic Law Journal

THE JOHN CREAUR LIBRARY
JUN 3 - 1960

MAY • 1960

From Bellyache to Headache—Is the Color-Additives Bill the Remedy?

WILLIAM W. GOODRICH

Medicated Animal Feeds Under the Food-Additives Amendment of 1958: A Case Study . . . . . .

ADRIEN L. RINGUETTE

See Table of Contents for Articles in This Issue

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $15 per year, including a handsome binder to hold one year's issues. Single copies are $1.50 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

May, 1960

Volume 15 • Number 5

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . May, 1960

		Page
Reports to the Reader About the Authors		293
Washington—Action and News In the Food and Drug Administration . . . In the Public Health Service		295
From Bellyache to Headache—Is the Color-Additives Bill the Remedy?	William W. Goodrich	297
Food Additives	John L. Harvey	305
Consumer Expectation—The Test of a Substance Natural to a Food as a Legal Defect	Ernest J. Schag, Jr.	311
Medicated Animal Feeds Under the Food-Additives Amendment of 1958: A Case Study	Adrien L. Ringuette	320
The Scientists' Forum	Bernard L. Oser	341

VOLUME 15 NUMBER 5

© 1960, Commerce Clearing House, Inc., Chicago 46, Illinois
All Rights Reserved

Printed in United States of America

Franklin M. Depew Is Elected President of The Food Law Institute

Franklin M. Depew is the newly elected president of The Food Law Institute, it was announced on May 17 by William T. Brady, chairman of the board of the institute. Mr. Depew, who has been with the legal department of Standard Brands, Inc., since 1934, succeeds the late Charles Wesley Dunn, who served as the institute's president from its inception in 1949 until his death in November of last year.

Mr. Depew is a member of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association; a former member of the Special Committee on the Revision of the Regulations of Practice at Hearings Before the Food and Drug Administration; and a charter member of the Division of Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association, and of its committee on food standards.

Best remembered by readers of the JOURNAL as editor, for several years, of the continuing feature "Notes and Comments," Mr. Depew was also coauthor of a volume on general state food and drug laws in The Food Law Institute Series. He has written numerous articles on various aspects of the food laws and he acts as special lecturer on food and drug laws in The Food Law Institute program at the New York University School of Law.

Mr. Depew and his family are residents of Plandome, New York.

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

Frank T. Dierson, New York City, *Acting Chairman;* Secretary, The Food Law Institute; General Counsel, Grocery Manufacturers of America, Inc.

Charles A. Adams, London, England, former Director, Food Standards and Labelling Division, United Kingdom Ministry of Food

H. Thomas Austern, Washington, D. C., General Counsel, National Canners Association

Fred Bartenstein, Rahway, New Jersey, Counsel, Merck & Company, Inc.

Robert E. Curran, Ottawa, Canada, Legal Adviser, Canadian Department of National Health and Welfare

William E. Fairbanks, New York City, General Counsel, Thomas J. Lipton, Inc.

A. M. Gilbert, New York City, Counsel, Best Foods Division, Corn Products Company

Robert S. Gordon, New York City, General Counsel, National Dairy Products Corporation

Edwin L. Harding, Battle Creek, Michigan, General Counsel, Kellogg Company

Harold Harper, New York City, General Counsel, National Wholesale Druggists' Association

James F. Hoge, New York City, General Counsel, Proprietary Association of America; Counsel, American Foundation for Pharmaceutical Education

Vincent A. Kleinfeld, Washington, D. C., former Food and Drug Law Attorney, United States Department of Justice

George Link, Jr., New York City, General Counsel, Charles B. Knox Gelatine Company, Inc.

Michael F. Markel, Washington, D. C., General Counsel, Corn Industries Research Foundation

Samuel A. McCain, New York City, Member, Executive Committee, The Food Law Institute; General Counsel, Corn Products Company

Bradshaw Mintener, Washington, D. C., former Assistant Secretary of Health, Education, and Welfare

Merrill E. Olsen, Chicago, General Counsel, Quaker Oats Company

C. Joseph Stetler, Chicago, Director, Law Department, American Medical Association

Walton M. Wheeler, Jr., Indianapolis, General Counsel, Eli Lilly & Company

Edward Brown Williams, Washington, D. C., former Principal Attorney, United States Food and Drug Administration

Julius G. Zimmerman, New York City, Member, Executive Committee, The Food Law Institute; Attorney, The Coca-Cola Export Corporation

THE EDITORIAL ADVISORY BOARD advises on policies, subjects and authors. It assumes no responsibility otherwise. Its members render this public service without compensation, in order that the FOOD DRUG COSMETIC LAW JOURNAL may comply with the highest professional standards.

Scientific Editor: Bernard L. Oser

Editor of Comments: Thomas W. Christopher

Editor of Cosmetic Law: S. L. Mayham

Editor of Canadian Law: Robert E. Curran, Q. C.

Editor of Foreign Law: Julius G. Zimmerman

Associate Editor for Europe: Ernst Abramson, M. D.

REPORTS

TO THE READER

About the Authors

An article dealing with the subject of color additives, written by **William W. Goodrich,** Assistant General Counsel for Food and Drugs in the United States Department of Health, Education, and Welfare, Washington, D. C., is featured in this May JOURNAL. It is derived from a speech which Mr. Goodrich delivered at a meeting of the legislative section of the Pharmaceutical Manufacturers' Association, at Boca Raton, Florida, on February 4, 1960.

Discussing the present regulatory plan, which he calls a "stringent one," Mr. Goodrich points out that on its face it looks like the ultimate in consumer protection—at least from the regulatory official's viewpoint. He notes three points in connection with it, however: (1) It is too rigid. (2) It covers "coal-tar colors," leaving unregulated or in the "debatable 'gray' area" some widely used materials which should be under the pretesting and certification program. (3) Experience indicates that prompt and thorough retesting of all colors on the supposed "harmless" list is needed. The FDA's facilities are inadequate; industry must be called into action.

Indicating that something has to be done to preserve proper coloring practices, Mr. Goodrich suggests that the prospects for some legislation now seem bright. He discusses the basic proposals of the color-additives bill and particularly the anticancer clause, which he terms "the only point that seems to offer the possibility of controversy."

In an article on food-additives petitions which were received prior to the middle of March of this year, **John L. Harvey,** Deputy Commissioner of Food and Drugs, notes that shortly after the enactment of the food-additives amendment of 1958 he made a kind of prediction that by March 6, 1960—the effective date—the United States Food and Drug Administration would probably have issued about 800 to 11,000 food-additives regulations authorizing use of additives under special circumstances. He adds: "Experience has shown that my crystal ball was very clouded when I made that prediction."

Going on—his article is taken from an address delivered before the Chicago Section of the Institute of Food Technologists, on March 14—he summarizes the petition status and answers the question: Where do we go from here? His article offers valuable information on a timely topic.

Ernest J. Schag, Jr., a 1959-1960 food-law fellow at the New York University School of Law, writes on "Consumer Expectation—The Test of a Substance Natural to a Food as a Legal Defect." He traces the development of case law in the area of natural-substance actions and warns that there is little doubt that a mere finding that the "bone of contention" was an indigenous substance in the food which caused the injury does not of itself save the supplier from liability.

Before going to New York University, Mr. Schag received an LL. B. degree from the University of Southern California. He is a member of the California bar.

Adrien L. Ringuette, an attorney in the office of the general counsel of Abbott Laboratories, North Chicago, Illinois, has contributed a case study of medicated animal feeds under the food-additives amendment. His paper, which was delivered at the annual meeting of the Animal Health Institute, in Washington, D. C., on April 18, discusses the Delaney anticancer clause as it pertains to feeds.

Noting that the widespread commercial addition of drugs to feeds is a "post-World War II phenomenon," he points out that by January, 1956, medicated feeds accounted for 20 to 25 per cent of all manufactured feeds. Still more amazing is his statement that today perhaps as much as 90 per cent of all animal feeds contain drugs for prevention or control of diseases or for growth promotion. These figures indicate why livestock feeds have become the subject of pressing regulatory problems.

Mr. Ringuette gives special attention to the organic arsenical compounds and to diethylstilbestrol. The latter is a hormone included in feeds for purposes of increasing weight and improving feed efficiency. Organic arsenical compounds are widely used in feeds for poultry and swine, for the same purposes and also as aids to control of disease.

Of diethylstilbestrol, he notes that this compound can be made to cause cancer in a few species of animals under certain conditions, but it cannot be made to cause cancer in most animals. Indicating that no cancer has been found in humans attributable to diethylstilbestrol despite wide medical use for two decades, he points out that diethylstilbestrol must still be considered a carcinogen if by "carcinogen" is meant a product which can produce cancer in any species of animal. Because of its being considered a "carcinogen," Mr. Ringuette notes, according to the Food and Drug Administration no food-additive regulation will be issued permitting its use in any feed; its existing use in feeds shall be strictly limited to the scope of its exemption from the food-additives amendment. He submits that, in the case of this particular drug, "the Delaney clause has operated to deprive . . . [its] safe use . . . from clearance."

Going on to organic arsenicals, he notes that arsenic in one form or another is ubiquitous in nature, has been used in medicine for hundreds of years, and for many years dominated important areas in agricultural pest control. Noting that arsenic occurs naturally in many foods for humans, Mr. Ringuette maintains that there has been "no reliable experimental evidence that any form of arsenic, organic or inorganic, can be made to induce cancer in animals." The only substantial evidence, he notes—involving *inorganic* arsenicals—is that massive long-term potassium arsenite therapy may produce a condition which *in turn* may cause cancer. According to the Food and Drug Administration, he says, no food-additive regulation can be issued permitting the use of any compound containing arsenic, including *organic* arsenicals, until the compound can be shown not to have any carcinogenic potential. However, scientists indicate that no one can show that any compounds cannot cause cancer. Mr. Ringuette says: "The cost of the Delaney clause to our growing society could prove enormous."

Mr. Ringuette is a member of the New York and the Illinois bars.

Bernard L. Oser, contributor of the continuing feature, "The Scientists' Forum," is president and director of Food and Drug Research Laboratories, of New York City.

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

Drug Reactions—Reporting Program.—A program for the reporting of unusual or adverse reactions to drugs was announced on May 4 by the Food and Drug Administration. The program will be conducted initially with a limited number of hospitals selected to represent a cross-section of medical specialties. Where necessary, contracts may be negotiated with the hospitals (or individual physicians designated by them) providing for reimbursement. As the program develops, it is planned that additional hospitals will be included, with the aim of establishing nationwide reporting. The project is an outgrowth of a voluntary pilot study carried out during the past four years in cooperation with the American Association of Medical Record Librarians, the American Society of Hospital Pharmacists, the American Medical Association and the American Hospital Association.

The program is designed to develop information promptly on the untoward effects of drugs, especially the newer drugs. The information will be utilized by FDA in the resolution of medical and administrative problems under the Federal Food, Drug, and Cosmetic Act.

Prior to release for general use, new drugs are required to be evaluated from the standpoint of safety by the Bureau of Medicine of the Food and Drug Administration. Notwithstanding a most careful check of the submitted data, wide clinical use may bring to light effects not apparent in the investigative studies. When these become known, appropriate measures are taken to afford a greater degree of patient protection. Remedial steps necessary on the part of the drug manufacturer or distributor may vary from a change in the labeling to alerting physicians and others responsible for patient care or to a complete removal of the drug from the market.

The Food and Drug Administration has previously had to rely on published literature and sporadic reports from physicians, institutions and pharmaceutical manufacturers to supplement its own small staff in following up on experience with new drugs.

New Technical Bulletin Issued.—The latest methods for microscope identification of contaminants in foods and drugs are now available in a new technical bulletin published by the Food and Drug Administration. *Microscopic-Analytical Methods in Food and Drug Control* is designed to help analysts trace adulterants to their sources, according to George P. Larrick, Commissioner of Food and Drugs. The 255-page bulletin is illustrated with 289 photographs and line drawings.

The 11 chapters cover product control and sanitation; sources and types of contamination; isolation and detection of contamination; microscopes, photomicrography, and exhibits; fungi associated with food decomposition; entomology in food and drug analysis; parasites and related forms; rodent and other animal filth in foods and drugs; applied histology of food and drug materials; crystallography and chemical

microscopy; and identification of drug tablets and capsules.

"We have made arrangements with the Superintendent of Documents to stock these bulletins for sale because we know that we are not the only ones concerned with the production of clean, unadulterated foods and drugs," the Commissioner said, in his announcement of the new publication. "The majority of manufacturers and handlers of foods and drugs are trying to furnish the consumer with products as free from contamination as it is possible to attain. This publication will be particularly helpful to the control departments of food and drug processing plants."

The bulletin replaces and enlarges the earlier *Microanalysis of Food and Drug Products*, first published in 1944 as Food and Drug Circular No 1. It was prepared by FDA's Division of Microbiology to show the scope of microscopic-analytical work; the approach used; and the application of such techniques to industry and regulatory problems.

Copies of *Microscopic-Analytical Methods in Food and Drug Control*—designated Food and Drug Technical Bulletin No. 1—may be obtained from the Superintendent of Documents, Government Printing Office, Washington 25, D. C., for $2 each.

Seizures During April, 1960.—Twenty-nine drugs and devices were seized during April, 1960, according to FDA's May report on enforcement and compliance, and all were alleged to bear false and misleading claims. Seventeen actions to protect the health and pocketbooks of consumers were taken during April against so-called "food supplements" promoted by false and misleading statements which suggested or implied that (1) all disease conditions are due to a faulty diet, (2) available foods do not meet nutritional needs of the average person and (3) the average person must supplement his diet with vitamin-mineral products to protect his health.

Five makes of devices were seized. These included a vibrator-massager chair; a so-called "ultra-sound" device; a foot exerciser; a so-called "air purifier" and a so-called "bust developer."

Food seizures included 47 tons of nuts, flour, spaghetti products, and spices seized in warehouses. The government alleged in seven of the 17 actions against warehoused foods that they were stored under insanitary conditions permitting contamination. Most of the volume of unfit foods removed from the market during the month—315 of the 491-ton total—was in wheat and flour with rodent, bird and insect contamination.

Thirty tons of dried lima beans in a single shipment were seized on charges that they were rodent-contaminated and had been held under insanitary conditions while in transit. Other foods seized as unfit were peanuts, pecans and pistachios that were rodent- and insect-contaminated, frozen whole eggs made with rotten eggs, and frozen seafood with parasitic cysts and spoiled fish.

Shipments of canned evaporated milk and a flour offered for special diets were removed from the market because of adulteration with pesticide chemicals not permitted in these foods. Two hundred and seventy-five tons of apple pomace silage contained DDT in excess of the legal tolerance for DDT on this animal feed. Illegal residues of this pesticide may get into human food by being deposited in the meat and milk of animals, FDA explained; enforcement of the tolerance is intended to protect consumers against adulteration of foods with chemicals.

Seized as economic cheats were so-called "chocolate chip" cookies with little or no chocolate; candy, frozen strawberries, and stuffed olives that were short-weight; and fresh-killed chickens offered under fanciful names.

(Continued on page 352)

Vol. 15, No. 5 May, 1960

Food·Drug·Cosmetic Law
Journal

From Bellyache to Headache– Is the Color-Additives Bill the Remedy?

By WILLIAM W. GOODRICH

The Author Says: Despite Differences over the Bill, a New Law Is Essential; Without It, Supposed Harmless Dyes Will Fall—One by One—from the Approved List. He Addressed the Legislative Section, Pharmaceutical Manufacturers' Association, at Boca Raton, Florida, on February 4, 1960

OUR PRESENT PROBLEMS with coloring matter for food, drugs and cosmetics originated, according to Sam Wheeler, with a small boy's bellyache, which developed into a severe headache for the entire regulated industries. Here we will consider a cure.

Mr. Wheeler's cure was a simple one indeed. We had only to correct our own erroneous interpretation of the law.

This interpretation was finalized, however, into delisting regulations despite the warning that it was in error. Three important colors available for unrestricted use in food, drugs and cosmetics were removed from the certified list because they could not be classified as harmless. Ultimately, the Supreme Court of the United States agreed with us that colors not themselves harmless are ineligible for food, drug or cosmetic use. The possibility that safe tolerances might be established or that colors might be limited to drug use only, so as to protect the public from hazardous amounts of toxic coloring materials, is not open to inquiry.

Mr. Goodrich Is Assistant General Counsel for Food and Drugs in the United States Department of Health, Education, and Welfare

As the unanimous decision of the Supreme Court pointed out, the present regulatory plan is a stringent one. If a color is an innocuous substance, no further inquiry can be made about it, and it may be freely used once it is listed and certified. If it is not a harmless substance, no further inquiry need be made. It cannot be used at all. The Department of Health, Education, and Welfare is not called upon to examine the safety of colors in the specific contexts of their uses in food, drugs and cosmetics.

This statutory plan, on its face, looks like the ultimate in consumer protection, at least from the viewpoint of the regulatory official. No chances whatever are taken. But the trouble is that it is too rigid and it offers the distinct possibility that substantially all available colorants may follow the seven already delisted off the approved list. Testing programs executed so far make this a practical certainty. Very few colors can measure up to the standard of harmlessness.

The second difficulty with this plan is that it covers "coal-tar colors," a term specifically defined only by regulation and not by the Act itself, leaving unregulated or in the debatable "gray" area some widely used coloring materials that should be under the pretesting and certification program.

Finally, experience plainly indicates that a prompt and thorough retesting of all the colors on the supposed "harmless" list is needed. The long-held assumption that all the listed colors are harmless is false. The exact toxicity of the colors is unknown. The Food and Drug Administration's facilities are inadequate and industry assistance must be called into action.

No one could be against colors in drugs. My own experience with the diseases of childhood has clearly illustrated the value of both

color and flavor. Any parent awakened at midnight by a fretful child and who has felt a feverish brow recognizes the merit of colored aspirin tablets. The red color that goes with wild-cherry flavor in some of our oral antibiotics has proved its value in fighting more serious infections. Getting a tablespoonful of *red* medicine down a sore throat is an easy task. A shot is completely unacceptable to an eight-year-old.

Something has to be done to preserve proper coloring practices. The color-additives bill, developed after many meetings with people who will be affected, is the Department's answer to the demands for a modern color-additives law. The Senate bill, amended to strike out the anticancer clause, has been passed without a dissenting vote. The House Committee on Interstate and Foreign Commerce has completed a week of hearings not only on the Senate bill, but also on the House bill which includes the anticancer clause. The prospects for some legislation seem bright.

Bill's Basic Proposals

The basic proposals of the color bill are as follows:

(1) Apply the new law to all coloring materials—not just coal-tar colors. Insofar as drugs are concerned, the operative part of the bill is concerned with coloring materials only if intended solely for coloring purposes, even though the basic definition of the term "color additive," which applies to food and cosmetic colors as well, is purposely a broad one.

(2) List all color additives but exempt from batch certification colors that can safely be marketed without batch testing.

(3) Erase the present regulatory plan at once and make a new start in the listing and certification of acceptable colorants for safe uses.

(4) Provide for an interim program of provisional listings and temporary tolerances for commercially established color additives, in order to permit completion of the scientific tests needed for making determinations as to the listing of the colors under the permanent part of the bill. Authority is provided to fix the temporary tolerance at a level found consistent with the protection of the public health, including, if necessary, zero level for any color or any color use.

(5) Authorize the Department to consider all the proposed uses of colors and to list and certify them for particular uses, and with

tolerance limitations when needed for the protection of the public health. This safe-for-intended-use plan is the essence of the recently enacted food-additives amendment.

(6) Condition final admission to the comprehensive list of acceptable coloring materials, whether coal-tar or not, upon sound and adequate scientific proof that no consumer harm can result from the approved uses.

(7) Extend the batch certification program, now applicable to coal-tar colors, to all colors not specifically exempted from it by a finding that certification is not necessary for the protection of the public health.

(8) Prohibit the approval of any color which may be ingested, if the substance is found to induce cancer when ingested by man or animal or after other tests appropriate for the evaluation of the safety of food additives, to prohibit other exposures to color, if tests relevant to such exposure show that the additive will induce cancer in man or animal.

(9) Deny approval to colors that will promote deception of the consumer or otherwise result in adulteration or misbranding and to colors which will not achieve the intended effect within the limits of a safe tolerance.

(10) Provide for establishing special packaging and labeling requirements for color additives to facilitate their safe use.

(11) Allow the Department to allocate a toxic color among the competing product demands for it where this is necessary to provide for its safe use.

Department Position re Anticancer Clause

The only point that seems to offer the possibility of controversy is the anticancer clause. Secretary Arthur S. Flemming has made a very strong case for it in his testimony before the House committee. This is grounded on the scientific fact of life that no one, at this time, can tell us how to establish a safe tolerance for a cancer-producing agent. No one knows how much or how little of a substance which produces cancer in test animals is needed to cause cancer in man or when the cancer may develop. Until cancer research makes a breakthrough at this point, there is no scientific basis on which discretion could be exercised in tolerating a small amount of a known carcinogen in food, in drugs or in cosmetics. When and if science can assure us

that a safe tolerance can be established, the Department will ask Congress to modify the anticancer clause. But with or without the clause, the Department must refuse to undertake the presently impossible task of establishing safe tolerances for carcinogens.

In giving his support to the anticancer clause, Secretary Flemming has attempted to clear up points of misunderstanding. He has, moreover, placed the Department on record as favoring an amendment to permit use of a carcinogen in animal feed, where it can be shown that it will not injure the animal as a food producer and where no residue whatever will remain in food for human consumption derived from the animal; also, he has suggested correction of the present situation in which some holders of new-drug applications continue practices, based on past approvals, which others cannot be permitted to undertake.

Secretary Discusses Practical Operation of Clause

In discussing the practical operation of the anticancer clause, Secretary Flemming said:

> Some of the opposition to inclusion of an anticancer provision . . . arises out of a misunderstanding of how this provision works . . . .
>
> It has been suggested that once a chemical is shown to induce a tumor in a single rat, this forecloses further research and forever forbids the use of the chemical in food. This is not true. The conclusion that an additive "is found to induce cancer when ingested by man or animal" is a scientific one. The conclusion is reached by competent scientists using widely accepted scientific testing methods and critical judgment. An isolated and inexplicable tumor would not be a basis for concluding that the test substance produces cancer.
>
> It has also been suggested that when a compound shown to produce cancer in test animals has been modified in chemical structure so that it no longer produces cancer, it continues to be incriminated by its past history. This, too, is erroneous. The Food and Drug Administration would—and should—take a close look at the modified compound to be certain it did not have the same cancer potential as its parent. But once convinced that the cancer potential had been eliminated, the anticancer clause would not preclude use of the substance.
>
> Finally, doubt has been expressed about the authority of the Department to reverse a decision in this area. This, of course, is an unfounded doubt. When new evidence is presented the Department has not only the right, but the obligation, to evaluate this evidence and determine whether a previous decision should be reversed.
>
> This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

No Ascertainable Threshold Dose for Carcinogen

We know that the Pharmaceutical Manufacturers' Association has been concerned about the anticancer clause. You would prefer to limit this clause to coloring substances which, in amounts reasonably related to intended uses, induce cancer in test animals. But this assumes an ascertainable threshold dose for a carcinogen—an assumption which is untrue according to the best scientific advice we can obtain.

Despite differences over this bill, most of which have been resolved, one thing is crystal clear. A new law is essential. Without a new law, the supposed harmless dyes will fall one by one from the approved list.

Scope of Color Use in Drugs

One need only look at our antibiotic regulations to glimpse the scope of color use in drugs. It is estimated that perhaps 50 per cent to 70 per cent of the new drugs in tablet, capsule and liquid dosage forms produced today contain color.

What, specifically, would a new law mean to the pharmaceutical manufacturer? He must first review his products to learn what colors are being used and in what amounts. This will be no small task. A single firm informed us some time ago that 68 of its products were colored with one or the other of the first three colors removed from the list. Then the manufacturer must be assured that the colors he is using are allowed. Where a tolerance is involved, he must be further assured that the tolerance allows his specific use.

Three-List Plan

Here is the crux of the new plan: The Department is directed to provide three lists—a food list, a drug list and a cosmetic list. A color may be approved for use in food generally, in drugs generally, in cosmetics generally, or it may be on all three lists for general use. More likely, however, it will be permitted under restriction. Where the safe tolerance for a color for use by man is 40 parts per million in his diet, and oleomargarine demands this amount, the drug manufacturer seeking an allocation for his product would have to compete for the color in terms of relative dependence for marketability and the availability of satisfactory substitutes.

This provision was objected to by PMA because it would be exceedingly difficult to administer and would demand knowledge which

FDA does not have and is unlikely to get. The suggestion was that we should turn to the food-additives amendment and prescribe tolerances for color on a first-come-first-served basis. This idea is fine where the tolerance is large enough to meet all demands or where one is seeking approval of a new practice rather than continuation of what he has long been doing. There is, however, sure to be a situation here where the tolerance will not go around. "First come first served" could result in using up the safe tolerance for a very important color on a relatively unimportant use, and there would be no means whatever to adjust the availability of the color to the uses for which it is most needed—indeed to the cases where its availability is critical to the survival of an important product.

This task will not be an easy one, but the criteria in the bill are the best yet suggested. Some means for adjusting uses to the demand are essential.

Education and Enforcement—New Problems

After the initial inventory of products and color uses has been completed, listings and tolerances established, and the colors approved for use in a variety of products under the necessary restrictions to protect the public health, both you in industry and we in the Department will find ourselves with entirely new problems of education and enforcement to provide assurance that the safe uses and safe levels permitted by the regulations are actually being observed.

We can no longer look on colors as innocuous substances. We must have a new awareness that colors certified safe by FDA are of the same order of toxicity as DDT, methoxychlor, and other well-known economic poisons. We must handle them with care, if their use is to be safe.

Because of the widely held belief that certified colors are wholly harmless, no one has yet bothered to gather reliable use information. I venture the opinion that many among this audience have no idea what colors are in your drugs or how much is used. This is typical. There has been no thought of danger here, and thus no need to know. If a new law is enacted, color will have to be controlled in the manufacturing process as closely as the most important drug ingredient, and at use levels measured in micrograms.

Regulatory Responsibilities

For FDA, a new law opens an entirely new regulatory problem. Inspectors have looked only for assurance that certified colors were

being used. The amounts and the product uses have been of no concern. Substantially the entire control system could be operated from a central laboratory testing and certifying colors as harmless. The new law would shift the responsibility for detecting misuses of color from the laboratory to the field inspector and the field laboratory. It will be a big job. It will take time and will cost money.

These new responsibilities are acceptable to us only because the alternative is to have almost no color additives at all.

Control is certainly not new to your industry, so there should be little trouble in using restricted colors safely. You will have to spread the word that color no longer may be treated as harmless and that its continued availability, as well as public protection, demands care in its use. The Administration will have to develop improved inspectional techniques to detect misuse of restricted colors.

This headache remedy will be a slow-acting one, but only because the underlying pathology is so complicated. We believe it will work.

[The End]

WEIGHT-REDUCING DRUG—TEMPORARY INJUNCTION UPHELD

In *U. S. v. Wilson Williams, Inc. and Jack Elliott,* decided in the United States Court of Appeals for the Second Circuit on April 27, it was held that a temporary injunction against interstate distribution of a weight-reducing drug was proper where it seemed probable that the government would prevail at the trial. The key charge in the complaint was that labels representing the drug as causing drastic weight losses without special diets amounted to misbranding in violation of the law. The complaint also alleged that more than 10 million tablets had been ordered by the defendants, a mail-order firm, for distribution in interstate commerce, and it appeared very unlikely that the defendants would be in a position to refund $14 to each purchaser, as had been promised if the drug did not accomplish the advertised weight loss.

In affirming the United States District Court for the Southern District of New York, the court of appeals commented on the injunction's propriety: "The proof on the government's application for a preliminary injunction overwhelmingly established the government's claims. The printed matter sent through the mails and with the . . . tablets would lead readers to believe that without any special diet they could lose many pounds in a few days—'9 pounds in 10 days! . . . 18 pounds in 20 days! . . . 27 pounds in 30 days! . . . up to 49 pounds in 8 weeks!'"

The court went on to describe other extravagant claims, noting that falsity and exaggeration were the only conclusions which could have been drawn from all the affidavits before the district court.—CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7588.

FOOD ADDITIVES

By JOHN L. HARVEY

Extension Requests, Petitions for Regulations, and FDA's Proposed Enforcement Policies Were Discussed in This Speech Before a Meeting of the Chicago Section, Institute of Food Technologists, on March 14

THE food-additives amendment to the Federal Food, Drug, and Cosmetic Act was enacted on September 6, 1958, following extensive consideration by the Congress of the need for more protection to consumers of food in this country. Fundamentally, it was intended to change the situation so that a manufacturer would be required to conduct adequate testing of food ingredients not generally recognized as safe rather than first putting these additives into our food supply and having the public eat them during a period while the Food and Drug Administration might be testing suspicious items which could turn out to be harmful. The evidence showed that the previous scheme of things had not worked and that the public had been exposed to harmful additives for some period of time before the Food and Drug Administration had been able to test them and acquire adequate evidence to get the items off the market.

As has been the custom in many earlier pieces of legislation, this one had several provisions which might be called "grandfather clauses." The Act started with the exemption of any (1) substances generally recognized as safe by qualified experts and (2) products for specific uses which had been granted prior sanction under the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act or the Federal Poultry Products Inspection Act. Not at all as a grandfather clause, the law also exempted pesticide-chemical residues on raw agricultural products, since these were adequately covered by the so-called Miller Amendment, enacted several years earlier.

The Author Is Deputy Commissioner, FDA

The food-additives amendment became effective for any new substance on March 6, 1959, but, to give time for the acquisition and evaluation of data, it provided the effective date to be March 6, 1960, for those additives which had been used prior to January 1, 1958. Anticipating that in some cases pharmacological work would be needed for some of these substances about which very little was known, toxicologically speaking, the amendment contained a provision authorizing administrative action to extend the effective date for up to one year under certain conditions which we will discuss later.

Early Prediction

The 18-month period between the time of enacting the amendment and the effective date for the previously used substances seemed to us to be quite liberal, and I recall making some sort of prediction that by March 6, 1960, we would probably have issued about 800 to 1,000 food-additive regulations authorizing the use of additives under special conditions and limitations. Experience has shown that my crystal ball was very clouded when I made that prediction.

Last summer, when the number of petitions received for regulations was still very small, we did our best to accept all engagements for talks at industry meetings to point out the necessity for more attention to the provisions of this law. In some areas this was somewhat successful, but there were certain areas where there was a sort of feeling, as one of our people put it, that if they paid no attention to the law it would go away. Try as we could, we began to think that our efforts were not at all successful. But pressure began to appear, from purchasers and from food distributors who were going to their

suppliers for assurance that the foods and components that were being sold them were not going to be in conflict with the terms of the amendment come March 6, 1960. Then we really had some action, but this did not get into high gear until about February 1.

Requests for Blanket Extensions

We began to receive some requests for blanket extensions of the effective date, but in each such case we had to point out that such blanket extensions were not possible. The provisions of the law require a finding that each extension granted is necessary and also that such an extension will not present any undue hazard to the public health for the period involved. Each extension request was given a separate file number and as of March 11, we had received 882 requests. Some of these extension requests covered but one product each, but we have some covering a great many. The highest number came from the Flavoring Extract Manufacturers Association, which submitted a list covering some 1,100 items. They had data on many of these, but not on all, and the items on this list are currently being studied. As the extension requests poured in, it became manifestly impossible for us to deal with all of these prior to the March 6 deadline, and so each one which, on its face and on quick review, looked reasonable was acknowledged by means of a form letter which included a promise that even though no decision had been made by March 6, we would not institute legal action without prior notice.

So far we have granted extensions for almost 700 items, many of which are in the field of food packaging which may migrate to the food. Right now, we have several hundred requests which have not yet been acted upon. It is not just a matter of getting enough people to handle the requests; instead, it is a matter of having adequate scientific personnel to evaluate each one. As is well known, we cannot find trained personnel overnight. I can assure you that none of the extensions are "automatic," even though I have seen that term used in one article which came to my attention. We insist that a careful review of the possibilities be made before any extension request is either granted or denied. I may say that in quite a few cases we have had to advise those who requested the extensions that we could not make a decision on the facts submitted and that we would need more information.

Just when we will be out of the woods on this extension matter I do not know, but I can assure you that we are doing our best.

During the past 18 months, we have had thousands of letters about the food-additives amendment and I do not know how many hundreds of meetings have been held with both our administrative and scientific people. As to the status of the food-additives correspondence, we have several hundred letters unanswered, although the greater number of these were received during the past two or three weeks. We are doing our best to get each answered.

Petition Status as of March 14, 1960

Perhaps you would be interested in the petition status as it now stands. As of March 14, we have received 136 petitions for food-additives regulations. So far, we have established ten regulations by publication in the *Federal Register*. Twenty petitions covered products which were not food additives, either because the item was generally recognized as safe or because it had a prior sanction. Fifty of the petitions could not be filed because they did not have enough information in them. The rest are still in the mill. As you may know, this law has very definite deadline procedures for the handling of petitions, and we are doing our best to stay within these deadlines.

Where do we go from here? A great many of the extensions of the effective date of the law have been or will be granted. I hope, however, that those who obtain these extensions will not feel a sense of accomplishment and sit back with the idea that there is nothing more to be done. I can assure you that this is furthest from the fact. The extensions are granted for only one year, and we can expect our food-additives office and our technical divisions to have a very busy 12 months. The regulations set up what should be submitted in a petition. I doubt that any of the items could be real stumbling blocks unless it is the one where we call for an adequate method of analysis for the item. The Food and Drug Administration is not going to issue any food-additive regulation unless there is a means by which we can enforce it. Would there be any real gain by establishing a regulation stating that 50 parts per million of Compound X is suitable for addition to spinach if we had no way of knowing whether a particular lot of spinach contained 500 parts per million? Nevertheless, we do not expect the impossible. We expect situations where we will be in

agreement with industry's conclusion that there is no adequate chemical method for determining the presence of certain food-packaging material migrants in foods and where, to the best of our scientific knowledge, there is no reasonable expectation that such a method can be devised.

In such cases, we stand ready to consider alternative methods whereby the regulations may be enforced. We are just about to publish an order dealing with such a packaging material where we will be able to check on its usage to determine whether the regulation limitations are being met. Our determination will be on the specifications of the packaging material as set forth in the regulation. I forecast that comparable methods may be devised as a means of solving other problems in this analytical field. Certainly, this presents a challenge to food technologists and, from my standpoint, I believe that it is a challenge that you will take up with the expectation that the problems can and will be solved. We stand ready to assist wherever possible.

"White Lists"

Let me make one comment about the so-called "white lists" we have issued, setting forth substances which, for certain uses, we regard as generally recognized as safe. These were put out in an attempt to be helpful to industry, and we expect to be able to publish more of these as time goes on. Certainly, however, the fact that a substance does not appear on these lists should not be taken as an automatic conclusion that that substance is a food additive. We have constantly advised inquirers that they are at liberty to make their own decisions as to whether a substance is generally recognized as safe. If they base a decision that a substance is not a food additive on sound data which is available to the scientific community generally, we anticipate no disagreement on our part. On the other hand, if the decision that a substance is safe is based only on scientific information available to a specific manufacturer but which has not been made available to the scientific community through appropriate publication, we think that a food-additive regulation may well be needed.

I am sure that there is a great deal of interest in the question of what enforcement policies the Food and Drug Administration proposes to follow now that the amendment is effective. We had heard stories that the Food and Drug Administration was readying a crack-

down to start on March 7 and that industry could expect an immediate onslaught of seizures, prosecutions and injunctions. It has now been a week since that date and we have not had any of these under the food-additives amendment. As we see it, this amendment has now become a part of the Federal Food, Drug, and Cosmetic Act which calls for investigational and enforcement policies which are squarely in line with the way in which we have gone about administering the other sections of the law over the years.

New Elements Entering into Factory Inspections

Our inspectors are continuing to make factory inspections, giving, of course, special attention to any direct or incidental additives which they may encounter. Certainly, they are having to get more detailed information about raw materials and packaging substances, as well as factory equipment, than we have asked for before. Where it appears to the district office that a report shows the use of a substance which may well be classed as a food additive, the facts will be referred to Washington for careful administrative and scientific review. If the substance in question is concluded to be a food additive for which no regulation or extension or pending extension is involved, only then will there be any determination of whether legal action should follow. As in the case of every other part of the law, the Food and Drug Administration is interested only in bringing sound actions where needed for the public interest, and there is no purpose on our part to build any sort of a record of actions in this or any other field of enforcement. **[The End]**

• MISREPRESENTATION—MEDICINAL PREPARATION •

A representation that a medicinal preparation will cure all kinds of arthritis, rheumatism, neuritis and bursitis has been challenged by the Federal Trade Commission. A Detroit drug firm and a Milwaukee individual, trading as a drug store, have been charged with misrepresentation.

Contrary to advertisements in newspapers and other media, the FTC complaint charges, the product will not arrest, correct nor cure any of these conditions nor is it an adequate, effective or reliable treatment. The tablets will not relieve severe aches and pains of the disorders or affected body muscles, as represented, but will merely give temporary relief of minor aches and pains, the complaint continues. It adds that the product is not a "new Wonder Formula" and will not help the "Body PRODUCE ITS OWN CORTISONE," as advertised.

The Detroit firm is a drug wholesaler selling the product to retail druggists; the individual sells it in his drugstore and by mail order. (Released April 27, 1960.)—CCH TRADE REGULATION REPORTS ¶ 28,705.

CONSUMER EXPECTATION—

The Test of a Substance Natural to a Food as a Legal Defect

By ERNEST J. SCHAG, JR.

In This Article Mr. Schag Traces the Development of Relevant Case Law to Determine How the Various Jurisdictions Have Considered Sharp Objects Which Are Natural to Particular Foods

IN CASES where a food consumer is injured by the presence of a sharp object in his food, there is a basic delineation between foreign substances and those which are natural or indigenous to the particular food. In the former class (such as iron filings in canned tomatoes, pebbles in canned beans, glass in bread, etc.), the presence of such foreign substance in the food is considered a legal defect. Therefore, a cause of action can be based either upon breach of implied warranty of fitness for human consumption or upon negligence.[1] But, generally, liability is not imposed for injuries resulting from the presence of the latter class. It has been said, for example, that bones "which are natural to the type of meat served cannot legitimately be called a foreign substance." [2] Likewise, cherry pits in cherry pie [3] and prune pits in prune butter [4] have been considered nonforeign to the dish served. However, in view of the fact that there is a limited body of authority to the contrary, it becomes necessary to determine

[1] Liability for injuries resulting from the presence of such foreign objects is usually clear, even though removing them would leave the remainder of the food edible. See Dickerson, *Products Liability and the Food Consumer* (1951), p. 184.

[2] *Mix v. Ingersoll Candy Company*, 6 Cal. 2d 674, 682, 59 P. 2d 144, 147 (1936).

[3] *Marnelos v. Anastasovites* (DC Mass., App. Div., March 9, 1933).

[4] *Courter v. Dilbert Brothers*, CCH Food Drug Cosmetic Law Reports ¶ 22,611 (N. Y. S. Ct., App. Term, 2d Dept., May 22, 1958).

The Writer, a New York University Food Law Fellow, Is a Member of the California Bar

the circumstances under which courts will or will not consider such natural substances as legal defects.

In a 1957 survey of natural-substance cases,[5] it was concluded that there was a clear-cut decisional trend holding no breach of the implied warranty of fitness for human consumption where the injury was sustained as a result of an indigenous substance left in the product because of the practical difficulties of removal. These cases, the writer stated, hold sellers not to a standard of perfection, but merely to one of reasonable care and fitness. Thus, as a matter of law, such substances did not render the food unfit for human consumption solely by reason of their presence.

Courts may well recognize the practical difficulties of removal and, further, that such substances are found in the food in its natural state, but these should not be, per se, the controlling factors. In cases sustaining a cause of action, the legal duty imposed upon the producer to keep his product absolutely clear of such substances would in turn depend upon whether the consumer in the particular situation would have reason to believe that no harmful objects, natural or otherwise, would be found in his food. Therefore, when it is said that negligence may not be predicated from the presence of substances natural to the product, what should be said is that there is no legal defect where, as a matter of common knowledge, consumers customarily expect the substance to be found in the particular dish served.

In tracing the development of the case law in this area, it would seem clearer that the consumer-expectation approach is the supporting rationale for findings that there is no legal defect in certain foods

[5] Wood, "The Effect of a Substance Natural to a Product on the Implied Warranty of Fitness," 12 *Food Drug Cosmetic Law Journal* 350 (June, 1957).

containing natural substances. Undoubtedly, the emergence of this rationale will provide a more consistent basis for judicial decision which will aid in formulating workable guides which are fair to both the food producer and the consumer. To decide this question as a matter of law, these guides should reflect actual consumer expectation and a high, yet practically attainable, degree of producer care.

In the leading case of *Mix v. Ingersoll Candy Company*, the plaintiff was injured by swallowing a fragment of a chicken bone contained in a chicken pie sold and served to the plaintiff in the defendant's restaurant. The Supreme Court of California affirmed the judgment sustaining the defendant's demurrer. The court found that the food furnished was reasonably fit for human consumption, and stated that "certain cases present facts from which the court itself may say as a matter of law that the alleged defect does not fall within the terms of the statute. . . . It is not necessary to go so far as to hold that chicken pies usually contain chicken bones. It is sufficient if it may be said that as a matter of *common knowledge* chicken pies *occasionally* contain chicken bones." [6] (Italics supplied.)

To many who have considered the subject, the *Mix* case stands for the proposition that there is no liability when injury is caused by a "natural" substance.[7] Perhaps this idea stems from the oft-quoted passage: "Bones which are natural to the type of meat served cannot legitimately be called a foreign substance. . . ." [8] It is important to note, however, that the court added "and a consumer who eats meat dishes ought to anticipate and be on his guard against the presence of such bones." In context, therefore, the reasoning is that where it is a matter of common knowledge that a substance is "occasionally" found in food, the consumer is deemed to expect to find it, and the burden is upon him to guard against it.[9] The test is not simply whether the substance is "natural" or not.

The *Mix* case was followed by a California district court in *Silva v. F. W. Woolworth Company*,[10] where the plaintiff sustained injury from a bone in a "special plate" of roast turkey. Even though the bone was claimed to have been in the dressing, the court looked upon the service as "one dish," in which there was no substance not "natural to the

[6] Cited at footnote 2.

[7] See Dickerson, work cited at footnote 1, at p. 185, where the author states that insofar as these cases rest on the notion of "naturalness" in the sense that nothing that is an inherent part of the raw product itself can be a legal defect, they do not hold water.

[8] Cited at footnote 2.

[9] Query: Is an "occasional" object sufficiently frequent to warn the consumer? See Dickerson, work cited at footnote 1, at p. 188.

[10] 28 Cal. App. 2d 649, 83 P. 2d 76 (1938).

type of meat served." The criterion for liability, "whether the object causing the injury was 'foreign' to the dish served" seems questionable, but the result is consistent with the *Mix* case.[11]

Precedent in Bone Cases Followed in Numerous Jurisdictions

The precedent set in the preceding two cases has been followed by a number of jurisdictions. In *Brown v. Nebiker,* injury and, ultimately, death were caused as a result of a sliver of bone in a pork chop served by the defendant's restaurant. The Iowa Supreme Court quoted from the *Mix* and *Silva* cases extensively, and affirmed the granting of a directed verdict to defendant. The court noted:

> If a sliver of bone is not a foreign substance in a chicken pie, or a turkey bone in turkey dressing, certainly small bones in a pork chop are not a foreign substance to the pork chop. One who eats pork chops, or the type of meat that bones are natural to, ought to anticipate and be on his guard against the presence of bones, which he knows will be there.[12]

A fragment of a pork bone was contained in a barbecued pork sandwich in *Norris v. Pig'n Whistle Sandwich Shop.*[13] The Georgia Court of Appeals affirmed a judgment of nonsuit, refusing to permit an inference of negligence from the mere presence of a particle of bone in a meat sandwich. Such a fragment in a food prepared from meat is something which one might ordinarily expect to find. The court also held that the presence of such an indigenous but inedible substance did not violate the Georgia food and drug laws as containing a "portion of an animal unfit for food." [14]

A turkey bone in "creamed chicken" was the cause of infection and resulting death in *Goodwin v. Country Club of Peoria.* Although the court recognized the importance of the implied warranty that food served shall be wholesome and fit, judgment for the plaintiff was reversed because such warranty was not breached. The Illinois court said:

> Such rule should be construed and applied in a reasonable manner, taking into consideration the "common experience of life." When viewed in this light, it must

[11] See also *Lamb v. Hill et al.,* 245 P. 2d 316 (Calif. DC App. 1952), where it was said that the customer had no right to expect an entirely boneless chicken pie in every instance; *Wieland v. Swanson & Sons,* CCH Food Drug Cosmetic Law Reports ¶ 22,413, 223 F. 2d 26 (CA-2, 1955), where the court found that whole bones are normally left in chicken as cut up for fricassee.

[12] 229 Iowa 1223, 1233-1234, 296 N. W. 366, 371 (1941).

[13] 79 Ga. App. 369, 53 S. E. 2d 718 (1949).

[14] In a later case, *Davidson-Paxton Company v. Archer,* 91 Ga. App. 131, 85 S. E. 2d 182 (1954), the same Georgia court recognized the principle of the *Norris* case, but refused to identify the "harmful object" in the turkey as a turkey bone, since evidence was introduced as to why it was not identified. Proof that it was a turkey bone was held to be defensive matter which the plaintiff was not required to negate.

be conceded that practically all meat dishes, whether they consist of beef, pork, fish, or fowl, do contain bones peculiar to the food being served.[15]

Among the more recent decisions is the New York case of *Lewis v. Cooperative P & C Family Foods, Inc.*,[16] where the court dismissed a consumer's complaint against a food market for breach of implied warranty and negligence in the sale of fish containing large pieces of bone. Unable to find precedent in New York, this tribunal followed the "criterion" of the *Silva* case: Was the object causing the injury "foreign to the dish served"? It was concluded that a fish bone in fish, being native and not foreign, could hardly be deleterious or make the fish unwholesome and unfit for human consumption. The plaintiff here contended that New York had not ruled out natural substances as a basis of liability, citing the New York cases holding trichinae in pork as a legal defect.[17] The court answered that trichinosis is not native to nor engendered by pigs; rather, it is a common disease or infection of pigs, that is, the entrance into, and multiplication within, the body as a pathogenic micro-organism, and not natural to the fresh pork. This reasoning is well taken, but assumes that "natural" is in itself the test.[18] The same result, consistent with the New York rule on trichinosis,[19] could have been more properly reached by finding that it was a matter of common knowledge that all fish contain bones.

The extent to which issues can be confused by a preoccupation with the "natural" v. "foreign" criterion is illustrated by the New York opinion of *Courter v. Dilbert Brothers, Inc.*[20] The plaintiff recovered against the retailer for injuries sustained from the consumption of prune butter containing a small fragment of prune pit and the retailer was awarded judgment over against the manufacturer. The defendant retailer's recovery on a cross-claim against the manufacturer for breach of warranty and negligence was reversed for failure to prove

[15] 323 Ill. App. 1, 8, 54 N. E. 2d 612, 615 (1944).

[16] CCH Food Drug Cosmetic Law Reports ¶ 22,630 (N. Y. S. Ct., Oswego Co., Motion Term, July 31, 1958).

[17] *McSpeden v. Kunz*, 271 N. Y. 131, 2 N. E. 2d 513 (1936); *Rinaldi v. Mohican*, 225 N. Y. 70, 121 N. E. 2d 471 (1918); *Catalanello v. Cudahy Packing Company*, 264 App. Div. 723, 34 N. Y. S. 2d 37 (2d Dept., 1942).

[18] See also *Shapiro v. Hotel Statler Corporation*, 132 F. Supp. 891 (DC Calif., 1955), where the court found that under the rule of the *Mix* case a fish bone was natural to "Hot Barquette of Seafood Mornay."

[19] In *McSpeden v. Kunz*, cited at footnote 17, the court said that "there are many people in this country who know nothing about trichinosis or the danger lurking in meats or the requisite heating point to destroy parasites." Other jurisdictions to the contrary have reached the same conclusion in trichinosis cases as natural-substance cases because the "possibility of danger from disease inherent in raw pork is a matter of ancient and general knowledge." (*Silverman v. Swift & Company*, 141 Conn. 450, 458, 107 A. 2d 277, 281 (1954).)

[20] Cited at footnote 4.

privity of contract.[21] On the manufacturer's appeal, before reaching the privity question, the court discussed the *Mix* rule and noted:

> It can be seen therefore, that a finding that a prune pit is a foreign substance is not in conformity with the case law of several sister states. Cases within our own state have involved many substances such as metal objects, stones, mice, bugs, worms, poisons, and other such items. While plaintiff's cause of action for breach of warranty is not directly involved on this appeal, nevertheless, serious doubt exists as to whether judgment should have been rendered in plaintiff's favor in the first instance.[22]

Such reasoning overlooks the sound basis for the *Mix* rule. It could hardly be found that a consumer would even occasionally expect to find a prune pit in a finely processed product sold as "prune butter."

Oyster-Shell Cases

Express judicial recognition of the consumer-expectation approach came from the Ohio Supreme Court in the 1960 case of *Allen v. Grafton*,[23] dismissing a plaintiff's cause of action for ingesting a piece of oyster shell—approximately 3 x 2 centimeters—in a serving of fried oysters. The presence of the shell did not justify the legal conclusion that the food was not reasonably fit for eating nor that it was "adulterated" within the meaning of the Ohio food and drug laws.[24] The court stated:

> The better test of what is legally defective appears to be what consumers customarily expect and guard against. . . . the possible presence of a piece of oyster shell in or attached to an oyster is so well known to anyone who eats oysters that we can say as a matter of law that one who eats oysters can reasonably anticipate and guard against eating such a piece of shell, especially where it is as big a piece as the one described in plaintiff's petition."[25]

The three dissenting judges agreed with the consumer-expectancy approach but found that a shell fragment of this size was not to be reasonably expected plus its being of such quality as might ordinarily render it injurious to health under the food and drug laws.

The foregoing cases have illustrated circumstances under which the courts have stated that the food consumed was not defective as a matter of law. In contrast, the following cases leave the question of reasonable fitness to the jury. However, it may be that they are not

[21] This court required proof of privity of contract for the negligence action as well because the piece of prune pit natural to the product was not deemed to be an inherently dangerous substance within the exception to the law of negligence created by *MacPherson v. Buick Motor Company*, 217 N. Y. 382, 111 N. E. 1050 (1916).

[22] Cited at footnote 4.

[23] 170 Ohio St. 249, 164 N. E. 2d 167 (1960).

[24] In *U. S. v. 1232 Cases . . . American Beauty Brand Oysters*, 43 F. Supp. 749 (DC Mo., 1942), the court found that the presence of shell fragments in oysters did not render them injurious to health and, thus, adulterated under Sec. 402(a) of the Federal Food, Drug, and Cosmetic Act.

[25] Cited at footnote 23.

entirely inconsistent with the rationale of the former cases. It is submitted that the main difference, apart from different foods involved, lies in the diversity of judicial opinion as to what constitutes common knowledge or consumer expectation.

In *Bonenberger v. Pittsburgh Mercantile Company*,[26] the plaintiff had purchased a can of oysters from the defendant retailer. While making oyster stew the plaintiff tasted the broth and swallowed a sharp oyster shell, which injured her esophagus. The majority of the court found that the defendant's evidence that oyster shells were part of the product in its natural existence was persuasive and relevant evidence but that the question of reasonable fitness for human consumption was for the jury. No authority was cited for such conclusion.[27] More can be said for the dissent, which considered that the warranty should be reasonably construed in light of common knowledge about the nature of the article sold. No sound reason could be perceived for arriving at a different conclusion in the case of an oyster shell in a can of shucked oysters than that of a cherry stone in a can of cherries or a splinter of bone in a T-bone steak. In each instance the potentially harmful substance is natural to the product sold; in each the likelihood of its presence, arising from practical difficulties of separation in the course of preparation for consumption, is a matter of common knowledge.

Instance of Bone in Soup Distinguished

In the Rhode Island case of *Wood v. Waldorf System, Inc.*,[28] the plaintiff, while eating chicken soup in the defendant's restaurant, had a chicken bone lodge in his throat. The defendant's argument that the bone could not be legally considered a foreign substance was rejected. The court assumed that chicken bones are natural to, and used in the preparation of, such soup, but did not think that it was necessary, natural or customary that harmful bones be allowed to remain in soup as finally dispensed to the customer. The soup was distinguished from foods which normally contain an obvious bone which the consumer ordinarily expects to find, because it was to be

[26] 345 Pa. 559, 28 A. 2d 913 (1942).

[27] An earlier case, *Roseberry v. Wachter*, 3 Harr. 253, 138 A. 273 (Del., 1925), considered a chicken bone in chicken noodle soup as a foreign substance. In a subsequent case, *DeGraff v. Myers Foods, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 22,600 (Pa. Ct. of Comm. Pleas, Bucks Co., 1958), where the plaintiff was injured by a chicken bone in chicken pie, the defendant's preliminary objections to the cause of action in the nature of a demurrer were overruled. The court recognized that the defendant's position represented the weight of authority, but felt constrained to follow the Pennsylvania rule in the *Bonenberger* case, which was said to be a minority of one to the contrary.

[28] 7 R. I. 1, 83 A. 2d 913 (1942).

ingested by drinking or direct swallowing without mastication, and the bone was concealed from ordinary observation.[29]

The New York court in *Lore v. De Simone Brothers*,[30] allowed recovery to a purchaser who sustained injuries when a sharp bone imbedded in a salami pierced the plaintiff's upper right palate. The court would not say that the fragment of bone was natural to a product composed of finely ground and processed meat encased in a skin or that a consumer who eats such a product ought to anticipate and be on his guard against the presence of such a bone. It is difficult to reconcile this decision with that of the other New York court in the *Courter* case, since the consumer would not expect to find prune pits in prune butter any more than bones in salami. The *Lore* case is more consistent with normal consumer expectation despite the fact that the object was "natural."

The 1959 case of *Bryer v. Rath Packing Company*[31] involved an action for negligence against the packer of sealed cans of "ready to serve boned chicken." The chicken was used in chicken chow mein, and served in a school cafeteria to a pupil, who was injured by a small chicken bone which lodged in her esophagus. A directed verdict for the defendant was reversed by the Maryland Court of Appeals, and the case was remanded for a new trial. The issue of reasonable fitness and safety was decided by reference to whether bones which are natural to the type of food eaten, but which are generally not found in the style of food as prepared, are to be deemed the equivalent of a foreign substance. The court considered the decisions as holding no liability for the presence of a natural bone,[32] but concluded that the instant case was more nearly akin to the cases relied upon by the claimant, which held the question of fitness to be for the jury.[33] The packer's attempt to distinguish the latter cases on the ground that, unlike this case, the foods involved did not require mastication, was rejected.[34] The court also felt that the packer of the chicken has

[29] While a consumer-expectation approach was mentioned, it is questionable whether the court actually applied it. A bone could just as easily be concealed in a chicken pie. Seemingly, the court merely imposed a higher duty on the manufacturer of a liquid product which required no mastication.

[30] CCH Food Drug Cosmetic Law Reports ¶ 22,535, 139 N. Y. L. J., No. 54, p. 13, 172 N. Y. S. 2d 829 (1958).

[31] 221 Md. 105, 156 A. 2d 442 (1959).

[32] *Mix v. Ingersoll Candy Company*, cited at footnote 2; *Silva v. F. W. Woolworth Company*, cited at footnote 10; *Brown v. Nebiker*, cited at footnote 12; *Goodwin v. Country Club of Peoria*, 323 Ill. App. 1, 54 N. E. 2d 612 (1944).

[33] *Wood v. Waldorf System, Inc.*, cited at footnote 28; *Bonenberger v. Pittsburgh Mercantile Company*, cited at footnote 26; *Roseberry v. Wachter*, cited at footnote 27.

[34] The fact that the food did not require mastication seems to have been the partial basis of the decision in *Wood v. Waldorf System, Inc.*, cited at footnote 28.

increased the amount of care necessary by expressly representing on the containers that the product was "ready to serve" and "boned." [35] He was thus required to exercise as much care as would enable users to rely with reasonable safety on his assurances. This was especially true where the packer had knowledge that the boned chicken would often be served in styles such as chicken chow mein, in which bones are not normally and naturally expected to be found.

Summary of Case Law

The studied development of the relevant case law leaves little doubt that a mere finding that it was an indigenous substance in the food which caused the injury does not of itself save the supplier from liability. Human experience has taught the consumer that food products such as meat, fish, poultry and fruit dishes are often sold containing natural, but sharp, inedible substances. The courts have generally recognized that the consumer expects to find some such substances in his food and that he should anticipate their presence and guard against them. Such food is deemed to be reasonably fit for human consumption, and the supplier has breached no duty nor implied warranty to the consumer. However, if the natural substance is of a type not normally found in the particular dish or if the supplier has led the consumer to believe that it will not be so found, a good cause of action is stated. While different jurisdictions may vary as to what the expectation may be in a particular situation, the increased utilization of this approach will, by eliminating preoccupation with "natural" as a test in itself, help formulate a more rational and consistent basis for judicial decision. **[The End]**

[35] *Cf. Lane v. C. A. Swanson & Sons*, CCH Food Drug Cosmetic Law Reports ¶ 22,395, 130 Cal. App. 2d 210, 278 P. 2d 723 (1955), where it was held that a can of "boned chicken" was expressly warranted to contain no bones. It is arguable that "boned chicken" means only that the principal bones have been removed and not that the product is "boneless." While the consumer might recognize that it is nearly impossible to remove all bones, the courts have not been willing to attribute any such reasoning to him.

By ADRIEN L. RINGUETTE

Medicated Animal Feeds Under the
of 1958:

IT SEEMS APPROPRIATE to approach the subject of the current legislative situation affecting the animal-health industry by focusing attention upon the pressing regulatory problems of the medicated-animal-feed industry, particularly pursuant to the food-additives amendment of the Federal Food, Drug, and Cosmetic Act. If in the course of this discussion I appear to trespass at times into the scientific domain, I ask forgiveness. It does seem rather difficult for the lawyer in the food and drug industry—as it surely is for the scientist—to separate science from law.[1]

Definition, Use and Importance

"Medicated animal feeds" have been defined as feeds for livestock which contain various drugs for medicinal or growth-promoting purposes. Actually, medications constitute only a few of the many substances which have come to be added to livestock feeds. For purposes of this article, however, it will be sufficient to confine discussion to the use of drugs in animal feeds.[2]

The widespread commercial addition of drugs to poultry and livestock feeds is a post-World War II phenomenon. By January, 1956, when the Food and Drug Administration sponsored a symposium on medicated feeds, such feeds accounted for 20 to 25 per cent of all

[1] For the views of an eminent scientist on the relation of law and science in the food and drug field, see Oser, "The Interdependence of Law and Science Under the Food, Drug, and Cosmetic Act," 9 *Food Drug Cosmetic Law Journal* 355 (June, 1954).

[2] The best general references to this subject are contained in the Proceedings of the *Symposium on Medicated Feeds* (Medical Encyclopedia, Inc., 1956), sponsored by the Veterinary Medical Branch of the Food and Drug Administration, January 23-24, 1956. Henceforth, this volume will be referred to as *Symposium*. See the following articles in the *Symposium:* Hunter, "History of Medicated Feeds," pp. 7-8; Lubbehusen, "Medicated Feeds, Some General Comments," pp. 9-14; Scoville, "Medicated Feed as an Economic Factor in the Livestock Industry," pp. 121-126; Briggs and Gay, "Public Health Significance of Drugs in Animal Feeds," pp. 156-158; Welch, moderator, "Panel Discussion," pp. 197-204.

the

58:

Food-Additives Amendment

A Case Study

The Author, an Attorney in the Office of the General Counsel, Abbott Laboratories, North Chicago, Illinois, Addressed the Annual Meeting of the Animal Health Institute, in Washington, D. C., on April 18, 1960, Discussing Application of the Delaney Clause to Medicated Feeds

manufactured feeds. Today the great bulk of manufactured feeds—perhaps as much as 90 per cent of all animal feeds—contains drugs for the prevention or control of specific livestock diseases as well as for the general purpose of growth promotion.[3]

Among the more widely used drugs routinely added to certain types of livestock feed, the organic arsenical compounds and diethylstilbestrol contribute importantly to the benefits provided by medicated feeds. Diethylstilbestrol is a hormone included in feeds to increase the weight and improve the feed efficiency of about 75 per cent of all beef cattle in feed lots in this country.[4] Organic arsenical compounds are widely used in poultry and swine feeds, chiefly for growth promotion and improvement in feed efficiency, and as an aid to control of disease.[5] Five such compounds are now in use in medi-

[3] The following statement found in the *Symposium* is illustrative of the variety of drugs contained in feeds: "Examples of drugs now routinely given to farm animals in the feed for various purposes include at least five different antibiotics . . ., several organic arsenicals, plus sulfaquinoxaline, nicarbazine, nitrophenide, nitrofurazone, furazolidone, and 2-amino-5-nitrothiazole. Several of these are used as growth-promotants, and others are used for the control or partial control of such diseases as scours in calves; baby pig diarrhea, dysentery, and necrotic enteritis in swine; and coccidiosis, hexamitiasis, respiratory disease, blue comb, infectious sinusitis, and blackhead in poultry. In addition, several hormone-like substances, such as stilbestrol or dievestrol diacetate, are used in beef cattle and poultry feeding. Also several anthelmintics, such as phenothiazine, are used to control Haemonchus, Ostertagia, and Trichostrongylus in cattle." (Briggs and Gay, *Symposium*, p. 156.)

[4] The popularity of diethylstilbestrol was established within a year after its introduction in beef-cattle feeds (Byerly, "Hormones in feeds," *Symposium*, pp. 17-27). For current data, see transcript, *Hearings before the Committee on Interstate and Foreign Commerce, House of Representatives, on Color Additive Amendments to the Federal Food, Drug, and Cosmetic Act* (1960), pp. 446-449, (testimony of Dr. Thomas Carney).

[5] Frost and Spruth, "Arsenicals in Feeds," *Symposium*, pp. 136-149.

cated feeds, accounting for as much as 16 million tons of broiler, laying and swine feeds annually.[6]

The use of medication in feeds has been a principal factor in revolutionizing feed technology, with important economic implications. It has both improved the efficiency of feed conversion and affected the organization of production on the farm, with a resulting higher production of meat, milk and eggs than would otherwise be possible. It was stated, at the symposium on medicated feeds, by representatives of the National Institutes of Health:

> As far as benefits to mankind from the use of medicated feeds are concerned, the main direct benefit is the present availability of more and better foods at relatively less cost to the producer and to the consumer.[7]

The revolution in feed technology constitutes an application of research of the first magnitude. It was made possible only through the advances of research on a broad front and through the synchronization of the research programs of private industry, of the colleges and of the government.[8] Earl L. Butz, dean of agriculture at Purdue University, recently wrote: "The use of chemicals is a principal reason for America's abundance of food and fiber."[9] Dr. Butz cited as illustrations of this conclusion marked improvement in the productivity of land and animals resulting largely from the use of chemicals and drugs. A striking example is the doubling of per-capita consumption of chicken meat in the last 15 years. According to Dr. Butz:

> The use of chemicals and pharmaceuticals completely revolutionized this industry, and has substantially made it possible for our good growers to produce one pound of chicken meat with two pounds of feed. This is phenomenal in a biological industry. It was undreamed of just two decades ago.[10]

Testifying before the Committee on Interstate and Foreign Commerce recently, Dr. M. R. Clarkson, Associate Administrator of the

---

[6] The five organic arsenicals are arsanilic acid, 3-Nitro-4-hydroxyphenyl arsonic acid, 4-Nitrophenyl arsonic acid, 4-Ureidophenyl arsonic acid, and arsenosobenzene. Frost, "Ten Year Record for Organic Arsenicals," *Feed Age*, May, 1960.

[7] Briggs and Gay, *Symposium*, p. 158. The authors state that factors leading to the increased popularity of medicated feeds include (1) the present availability of low-cost, stable and efficient drugs for specific diseases and of effective hormone-like materials, (2) the ease, effectiveness and safety of administering drugs in the feed to large numbers of animals on a daily basis and (3) the remarkable growth of the modern feed industry.

[8] Butz, "The Impact of FDA Regulations on Research and Living Standards," *Feedstuffs*, March 26, 1960, pp. 10-12. Reviewing the remarkable record made by medicated feeds, one of the participants in the symposium on medicated feeds said: "It was made because research resulted in the finding of chemicals of outstanding efficiency in preventing clinical outbreaks of several infections that represented universal problems of the poultry industry; hence the probable need for preventive medication could be projected with a fair degree of accuracy in the light of past experience." (Lubbehusen, *Symposium*, p. 10.)

[9] Butz, work cited at footnote 8, p. 11.

[10] It should be noted that the importance of drugs in feeds was emphasized at the symposium. See Boughton, "Anthelmintics in Animal Feeds," *Symposium*, p. 61, who said: "We have passed the point at which only the so-called natural feed materials rate consideration as feed ingredients."

Agricultural Research Service, Department of Agriculture, emphasized the research and development of chemicals for use in crops and in livestock production as important factors in our agricultural economy.[11] This is a continuing role. As Dr. Clarkson pointed out, within 50 years farmers will need to produce at least twice their present crop output and more than twice their present production of livestock products. New applications of research and new technology will therefore be required.

Regulation as Drugs

Prior to the enactment of the food-additives amendment of 1958, the drugs then in commercial use in feeds had all been extensively tested by their manufacturers and cleared as safe for their intended use by the Food and Drug Administration.

When first introduced into commerce, these drugs were considered as new drugs subject to the requirements of the new-drug section of the Federal Food, Drug, and Cosmetic Act except that medicated feeds containing antibiotic drugs are regulated under the antibiotic-certification section of the Act.[12] Under the new-drug section,[13] no manufacturer can market a new drug unless an application filed with the Secretary of Health, Education, and Welfare is effective. Effectiveness may be withheld unless the application contains data to show that the drug is safe under the conditions of its intended use. It is apparent that the law calls for the pretesting of new drugs by manufacturers and for evaluation by the Secretary of the likelihood of harm resulting from the proposed use of a drug.

However, medicated animal feeds were also subject to the food provisions of the Federal Food, Drug, and Cosmetic Act. It was there provided that any poisonous or deleterious substance added to any food, except where such substance is required in the production

[11] Transcript, *Hearings* cited at footnote 4, at pp. 629-636.

[12] Meyers, "New Drug Status of Medicated Feeds," *Symposium*, pp. 66-69; Jester, "The Antibiotic Regulations for Medicated Feeds," *Symposium*, pp. 50-52; Kneeland, "Medicated Feeds and the Federal Law," 12 *Food Drug Cosmetic Law Journal* 359 (June, 1957). Section 507 of the Federal Food, Drug, and Cosmetic Act provides for certification of batches of drugs composed wholly or partly of penicillin, streptomycin, chlortetracycline, chloramphenicol or bacitracin, or any derivative thereof. Thus, a medicated feed containing one of these antibiotics is governed by this section. Such a feed, even though additionally containing other drugs, is excluded from the new-drug provisions of the Act. Each batch must be certified by the Food and Drug Administration unless the feed is exempted from certification by regulations promulgated by the FDA. But since exemptions are granted only upon the presentation of data proving that the drug combination is safe and efficacious for use, the antibiotic regulations tend to approximate the same degree of control as is exhibited under the new-drug section.

[13] Federal Food, Drug, and Cosmetic Act, Sec. 505.

thereof or cannot be avoided by good manufacturing practice, is deemed to be unsafe.[14] The operation of this provision, as distinguished from the new drug-section of the Act, does not depend upon evaluation of the likelihood of harm resulting from the proposed use of an additive. Rather, it merely calls for inquiry as to whether the additive is sufficiently toxic to be classed as a "poisonous or deleterious substance." [15]

The classification of medicated feeds as drugs made it necessary for manufacturers of new medicaments to obtain effective new-drug applications prior to introducing them into commerce. But the classification of meat and other products from livestock as "food" enabled the Food and Drug Administration to consider residues of drugs contained in such food products as poisonous or deleterious substances, thus rendering the food products adulterated unless the drugs are necessary for the production of meat or other products used for food.[16] In a policy statement published in the *Federal Register* on December 4, 1948, the Food and Drug Administration declared that in the case of drugs intended to effect physiological changes in farm animals, as distinguished from drugs intended for the prevention or treatment of animal disease, manufacturers were required to show that, under the conditions of use, residues of the drugs were eliminated from the livestock prior to marketing.[17] Tolerances were not to be granted such residues even though their safety could be established.[18]

The problems were worked out under the vigilance of the Food and Drug Administration and with the cooperation of drug manufacturers, the feed-manufacturing industry, colleges, research laboratories, and feed-control officials, with the result, as indicated by representa-

[14] Federal Food, Drug, and Cosmetic Act, Sec. 406(a). The history of this section is outlined in Markel, "The Food Additives Amendment of 1958," 14 *Business Lawyer* 514 (1959).

[15] From the point of view of evaluation of safety, the term "poisonous or deleterious substance" is not meaningful. Consider the following statement of the Food Protection Committee: "There need be no hazards involved in the use of chemical additives in foods, provided adequate scientific research programs are carried out prior to the use of an additive. The fact that a chemical is toxic does not mean *per se* that its proper use as an additive will entail a hazard to man." Food Protection Committee, Food and Nutrition Board, *Use of Chemical Additives in Foods* (publication of National Academy of Sciences, National Research Council, 1951).

[16] The policy of the Food and Drug Administration is illustrated in the following papers prepared by representatives of this agency: Collins, "The Problem of Drugs for Food-Producing Animals and Poultry," 6 *Food Drug Cosmetic Law Journal* 872 (November, 1951); Moskey, "Drugs in Animal Feeds," 8 *Food Drug Cosmetic Law Journal* 108 (February, 1953); Meyers, *Symposium*, pp. 66-69; Kneeland, work cited at footnote 12.

[17] Kleinfeld and Dunn, *Federal Food, Drug, and Cosmetic Act, Judicial and Administrative Record 1938-1949*, p. 759.

[18] On the other hand, tolerances could be granted for residues of drugs intended for the prevention or treatment of animal disease on the ground that such use of those drugs was necessary in the production of livestock. In such cases tolerances would be granted only if shown to be safe. (Meyers, *Symposium*, p. 69.).

tives of the National Institutes of Health, that no drugs are used in medicated feeds that have not been proved to be safe.[19] Their conclusion that "the benefits of medicated feeds far outweigh any evidence of possible danger to mankind from their use" seems amply justified.

Regulation as Food Additives

The provisions of the food law prohibiting the addition of any poisonous or deleterious substance to any food were generally considered unsatisfactory. On the one hand, such provisions did not authorize the use of substances which might be desirable and safe at low levels of use but toxic at higher levels. On the other hand, they were impractical to enforce effectively in the absence of any requirement of pretesting of additives by their manufacturers. The food-additives amendment of 1958 was designed to remedy these conditions.[20]

The House Committee on Interstate and Foreign Commerce, reporting this legislation, stated:

> The purpose of the legislation is twofold: (1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels.[21]

[19] Briggs and Gay, *Symposium*, pp. 156-158.

[20] The legislative history of the food-additives bill amply bears out this conclusion (H. Rept. 2284, 85th Cong., 2d Sess., Committee on Interstate and Foreign Commerce, House of Representatives, July 28, 1958; S. Rept. 2422, 85th Cong., 2d Sess., Committee on Labor and Public Welfare, United States Senate, August 18, 1958). See the summary of the legislative history of the bill recently made by Edward Brown Williams for the Pharmaceutical Manufacturers Association (*Hearings*, cited at footnote 4, at pp. 518-542). As early as 1956, the Food and Drug Administration supported a policy to relax the flat prohibition against unnecessary or avoidable poisons in food as contained in the 1938 Federal Food, Drug, and Cosmetic Act. (*Hearings before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, on Bills to Amend the Federal Food, Drug, and Cosmetic Act* (1956), pp. 193-194 (testimony of George P. Larrick, Commissioner of Food and Drugs)). The importance of this decision was described a few months later by the Assistant Secretary, Department of Health, Education and Welfare. "This was a far-reaching step. It means abandonment of the *per se* rule and would be a modification of the 'necessity' rule. It would mean that any chemical additive—even a known poison — could be used in a harmless amount, provided it would serve some useful purpose in production or be of benefit to the consumer. In my opinion, this is a scientifically sound position." Mintener, "The Food-Additive Problem," 11 *Food Drug Cosmetic Law Journal* 621, 626 (December, 1956). The responsible scientific community takes a similar view. See footnote 15. For illustrative discussions of the dual inadequacy of the 1938 Act with respect to food additives, see Snyder, "An Appraisal of the O'Hara Bill (H. R. 9166, Eighty-Third Congress) to Provide for the Pretesting of New Chemical Additives to Food," 9 *Food Drug Cosmetic Law Journal* 693 (December, 1954); Foster, "Food-Ingredient Legislation," 10 *Food Drug Cosmetic Law Journal* 82 (February, 1955); Miller, "Chemicals in Food," 10 *Food Drug Cosmetic Law Journal* 104 (February, 1955); Markel, "Food Additives," 10 *Food Drug Cosmetic Law Journal* 769 (November, 1955); Gosnell, "Food-Additive Legislation—A Review of Fundamentals," 12 *Food Drug Cosmetic Law Journal* 369 (June, 1957).

[21] H. Rept. 2284, 85th Cong., 2d Sess., Committee on Interstate and Foreign Commerce, House of Representatives, July 28, 1958.

The provisions of the food-additives law, in the absence of the Delaney clause, which we will discuss presently, probably would not have adversely affected the animal-health industry. Pursuant to the law, a substance which falls within the definition of a food additive, including a substance added to animal feed, is declared unsafe, unless there is in effect a regulation prescribing the conditions under which such additive may be safely used. In theory, at least, medicated animal feeds meeting the safety requirements of both the new-drug law and the food-additives laws are feasible.[22] Furthermore, existing feed medications, having been reviewed by the Food and Drug Administration, are considered exempt from re-examination under the food-additives law pursuant to the prior sanction or the general recognition of safety exemptions contained in the law.[23]

If a medicated feed is not exempt, it is necessary to obtain a regulation prior to marketing it but by virtue of a clause in the food-additives law, known as the "Delaney clause," a regulation cannot issue permitting use of the additive:

> . . . if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

This clause has been interpreted to limit the discretion of the Food and Drug Administration in respect to compounds having the capacity to cause cancer. Such compounds are thus distinguished from compounds which have the capacity to cause any other disease or which may be toxic at some level.

---

[22] It is clear that drugs added to animal feed must contend with both the food-additives law (Sec. 409) and the new-drug law (Sec. 505). Insofar as both laws are designed to permit the marketing of safe products, however, presumably safe products can be cleared under both laws. But the overriding problem is whether the Delaney clause (Sec. 409(c)(3)(A)) can be reconciled with the basic principles of these laws. (Hagan, "The Food-Additives Amendment — Its Effect on Veterinary Drugs and Feeds," 15 *Food Drug Cosmetic Law Journal* 117 (February, 1960); Checchi, "Food-Additives Procedures and Policies," 14 *Food Drug Cosmetic Law Journal* 591 (September, 1959); Oser, "Current Problems Posed by the Food-Additives Amendment," 14 *Food Drug Cosmetic Law Journal* 574 (September, 1959). The food-additives law is not without problems, however. See Oser, "Food Additives—New Law Causes Many Problems," *Chemical and Engineering News*, February 15, 1960, p. 108; Mulford, "Some Vexing Problems of Additives Under the New Law," 15 *Food Drug Cosmetic Law Journal* 10 (January, 1960); Hutchings, "The Food-Additives Amendment as Seen by the Technologist," 15 *Food Drug Cosmetic Law Journal* 17 (January, 1960); "FDA Answers to Questions Submitted at Washington Conference on November 24-25, 1958, to Discuss Food-Additives Amendment," 14 *Food Drug Cosmetic Law Journal* 5 (January, 1959).

[23] Federal Food, Drug, and Cosmetic Act, Sec. 201(s). There are also problems that have not been resolved in the matter of exemptions, for it appears that there are rather sharp differences of opinion as to the scope of both exemptions, particularly as applied to veterinary drugs. See Hagan, work cited at footnote 22. One perplexing problem is the matter of general recognition of safety. For the Administration view, see Goodrich, "The Beginning Point Under the Food-Additives Amendment—What Substances Do Qualified Experts Generally Recognize as Safe?" 14 *Food Drug Cosmetic Law Journal* 584 (September, 1959). See, also, the references contained in footnote 22.

The basic principle of the food-additives law, however, in order to accomplish both of its purposes, is that a food additive shall be approved for a particular use unless a fair evaluation of the data fails to establish that the additive will be safe under the conditions of its use. The legislative history of the bill sets forth the applicable concept of safety.[24] Safety requires proof of harmlessness under the conditions of use and not proof of absolute harmlessness under any conceivable circumstances. This calls for the exercise of scientific judgment.[25]

The argument for setting apart compounds which have the capacity to cause cancer is that in the present state of our scientific knowledge we cannot be certain that any use of a demonstrated carcinogen is safe. This argument has now been taken up by the Secretary of Health, Education, and Welfare as the reason for endorsing the Delaney clause.[26] Examining the operation of the Delaney clause upon the animal-health industry, our object is to determine whether or not the Delaney clause is consistent with the basic principle of the food-additives law.

Diethylstilbestrol is a compound which can be made to cause cancer in a few species of animals under certain conditions. It cannot be made to cause cancer in most animals, however, and no cancer in humans has been found attributable to diethylstilbestrol despite its wide medical use in humans, for 20 years, encompassing hundreds of thousands of patients. Furthermore, many common foods normally contain estrogens similar in physiological effects to diethylstilbestrol. Estrogens are part of the normal background of all of us.[27]

---

[24] H. Rept. 2284, 85th Cong., 2d Sess., Committee on Interstate and Foreign Commerce, House of Representatives, July 28, 1958; S. Rept. 2422, 85th Cong., 2d Sess., Committee on Labor and Public Welfare, United States Senate, August 18, 1958. See, also, Food Protection Committee, Food and Nutrition Board, *Principles and Procedures for Evaluating the Safety of Food Additives* (Publication 750 of National Academy of Sciences—National Research Council) (1960), at p. 1, which states: "Results of critically designed studies of the physiologic, pharmacologic, and biochemical behavior of a proposed additive in various species of animals can provide a basis for evaluation of its safety at a specified level of intake by man. It is impossible, however, to establish absolute assurance that the additive at any level of intake will be completely safe for all humans under all conditions." This concept was also adopted by the *Report of the Joint FAO-WHO Expert Committee on Food Additives* (1956).

[25] Matson, "Scientific Judgment in Law and Regulation," 15 *Food Drug Cosmetic Law Journal* 70, 75 (January, 1960). Dr. Matson stated: "The science of pharmacology performs on the basic assumption that research over a reasonably short period of time combined with insight as to the probable significance of the results will permit the acceptance of food additives as safe for human beings with substantially no hazard involved. This is the essence of scientific judgment."

[26] Transcript, *Hearings*, cited at footnote 4, at pp. 19-34.

[27] Paper entitled "Safety of Diethylstilbestrol," transmitted to Committee on Interstate and Foreign Commerce, February 11, 1960, and summarized at pp. 447-455 of the transcript, *Hearings* cited at footnote 4. See, also, "Panel Discussion: Feeding

(Continued on next page)

Diethylstilbestrol must be considered a carcinogen, however, if by "carcinogen" we mean a product which will produce cancer in any species of animal. Therefore, according to the Food and Drug Administration, no food-additive regulation will be issued permitting the use of diethylstilbestrol in any feed. Its existing use in feeds shall be strictly limited to the scope of its exemption from the food-additives law.[28]

The evidence is overwhelming, however, that diethylstilbestrol has been shown to be safe when used in animal feeds as previously sanctioned by the Food and Drug Administration.

The Food and Drug Administration has examined data presented for six different uses of diethylstilbestrol, and new-drug applications pursuant to the new-drug section of the Federal Food, Drug, and Cosmetic Act have become effective for each use. The drug has been used in human medicine since 1941 and in the feed of beef cattle since 1954. The elimination of the drug from the food obtained from livestock fed diethylstilbestrol was demonstrated to the satisfaction of the Food and Drug Administration, in accordance with its policy regarding medicated feeds as previously described. But even if undetectable residues were to exist in beef, the amount of the drug reaching our food supply would be insignificant in relation to the therapeutic dose of diethylstilbestrol and to the natural estrogenic background.[29]

It is submitted that in the case of diethylstilbestrol, the Delaney clause has operated to deprive a safe use of this drug from clearance. This violates the basic principle of the food-additives law. Scientific judgment has been entirely excluded.[30] This is a step backward, since

(Footnote 27 continued)

Diethylstilbestrol to Cattle," *Symposium*, pp. 170-177. Dr. Gassner, head of the Endocrine Section at Colorado A. & M. Experimental Station, said: "Thus it seems that man and animal alike are forced normally to maintain a high threshold of response to estrogen and that the human is rendered relatively insensitive to the infinitesimally small amounts of hormone that possibly could be ingested with meat products." (*Symposium*, p. 173.)

[28] See 21 CFR Sec. 3.37, "Status of certain veterinary drug components under the food additives amendment to the federal Food, Drug, and Cosmetic Act," published May 30, 1959, at 24 *Federal Register* 4376. The policy statement was a general statement applicable to compounds falling under the Delaney clause. Diethylstilbestrol was held to fall within the Delaney clause. See *Food Chemical News* for June 22, 1959.

[29] See footnote 27. Dr. A. H. Holland, Jr., Veterinary Medical Director of the Food and Drug Administration, said (*Symposium*, p. 176): "Our position, I think is very clear. All of the work, all of the literature we have had occasion to study and review over a period of many, many months preponderantly led to the conclusion that diethylstilbestrol as proposed for use in cattle feed was perfectly safe."

[30] It is perhaps significant that certain scientists advocating the prohibition of diethylstilbestrol are also among those who do not accept the exercise of scientific judgment in evaluating food additives. Consider the paper by Knight, Martin, Iglesias and Smith, "Possible Cancer Hazard Presented by Feeding Diethylstilbestrol to Cattle," *Symposium*, pp. 167-169. That their paper was based upon "speculations" and "theoretical considerations"

even the 1938 Act, with its per se rule on poisonous or deleterious substances, did not prohibit the clearance of diethylstilbestrol under the Federal Food, Drug, and Cosmetic Act. It is not sufficient, however, merely to re-establish the 1938 Act for diethylstilbestrol, for the 1938 Act would prohibit even insignificant residues of any drug in relation to the normal background. Such residues can be determined to be safe.[31]

Organic arsenicals provide another case in point.[32] Arsenic in one form or another is ubiquitous in nature. Arsenic compounds have been used in medicine for hundreds of years and for many years they dominated important areas in agricultural pest control. Between 1910 and 1945, organic arsenicals provided the best medical tools against man's most serious parasitic diseases such as syphilis. Arsenic occurs *naturally* in many foods we eat, including eggs and the tissues of

(Footnote 30 continued)

was indicated by the panel discussion that followed (pp. 170-177). Dr. W. Coda Martin, president of the American Academy of Nutrition, testified the following year that the academy approves of the concept of total nutrition, which means food free of chemical additives. He further said: "The human body can utilize only natural foods as nourishment and survive. Chemicals are not food elements. Therefore, they can produce only negative or harmful results, even though they are by scientific analysis nontoxic." (*Hearings* (1958), pp. 272, 279.) Dr. W. E. Smith, also associated with the American Academy of Nutrition, said: "I submit that the adulteration of food with new chemicals is not a right, but a privilege that should be permitted only when there is real need." (*Hearings* (1958), p. 173.) In a letter to Congressman Delaney, he said: "It is simply not in the public interest to expose consumers to the unforeseeable risks of a host of biologically foreign food additives that may provide eye-appeal or advertising values but offer no nutritive benefit." (Extension of remarks of James J. Delaney, 103 *Congressional Record*—Appendix, pp. A1351-A1354, February 21, 1957) (letter dated January 28, 1957). These opinions clearly are not compatible with the scientific community as a whole or with the philosophy of the food-additives law. See footnote 15.

[31] See Matson, work cited at footnote 25, at p. 80. Dr. Matson stated: "We must provide that scientists of the Food and Drug Administration shall be permitted to use reasonable scientific judgment, not giving regulatory recognition to those trace amounts of a food additive so distantly related to the amount and duration of use known to constitute a hazard that no purpose is served by recognizing them." The validity of this conclusion is at least implied in the publication of the Food Protection Committee, Food and Nutrition Board, *Problems in the Evaluation of Carcinogenic Hazard from Use of Food Additives* (Publication 749 of the National Academy of Sciences—National Research Council) (1960), which states at p. 32: "The assignment of a tolerance level, or a safe level of use for man, of a demonstrated carcinogen must at present rest largely on the evaluation of alternate risks and values which usually cannot be expressed in quantitative terms. Quantitative knowledge about the carcinogen, e.g., the slope of the dose-responsive curve, the maximum experimental no-effect level, the minimum technological amount necessary for the proposed use, can, however, be taken into account in assigning such a tolerance level." Several of the scientists appearing before the Committee on Interstate and Foreign Commerce on April 5-6, 1960, expressed the opinion that tolerances might well be set for "weak" carcinogens. (For example, Dr. Charles J. Kensler, *Hearings* cited at footnote 4, at p. 743.

[32] Summaries of the data pertaining to arsenicals appear in the following: Frost and Spruth, *Symposium*, pp. 136-149; Frost, work cited at footnote 6, and "Arsenic and Selenium in Relation to the Food Additive Law of 1958." *Nutrition Reviews*, May, 1960; Frost, Perdue and Overby, "Arsenicals in Feeds and Their Residues in Animal Tissues," address presented at Symposium on Chemical Residues in Agriculture, Michigan State University, January 26-27, 1960; Frost, "Considerations on the Reality of 'Arsenic' Cancer," unpublished manuscript dated September 30, 1959; Kerr, "A Review of the Literature Pertaining to Arsenic as a Carcinogen," unpublished manuscript dated June 23, 1959.

poultry. Arsenic occurs naturally in soils and vegetation, and sea water contains traces which are concentrated to high levels in marine algae and crustaceans. Arsenicals have been more widely studied and widely used in medicine and in agriculture than, perhaps, any other class of compounds, yet there has been no reliable experimental evidence that any form of arsenic, organic or inorganic, can be made to induce cancer in animals. Neither does the medical literature in any way implicate organic forms of arsenic as a carcinogen for man.[33]

There has been a great deal of speculation tending to implicate inorganic forms of arsenic as carcinogens.[34] The only substantial

[33] It should be noted that in the recent pamphlet cited at footnote 31, the only references to arsenic are that inorganic arsenic compounds are listed as agents "associated" with cancer incidence in man, and that arsenic trioxide is a compound which has been reported to be a carcinogen for animals but for which evidence of activity is inadequate.

[34] The first implication of arsenic as a possible carcinogen dates back to 1822, and was based on arsenic in fumes from smelting works. Since that time, cases of cancer in man have been attributed to inorganic forms of arsenic to which the individuals had been exposed. These cases involved occupational exposure (for example, vineyard workers, miners and smelter and factory workers), environmental exposure (for example, excessive arsenic in drinking water in Germany and Argentina), and medicinal exposure (chiefly potassium arsenite therapy). See references at footnote 32. That these observations are largely speculative—with the exception of the medical cases—is illustrated by Eckardt, *Industrial Carcinogens* (1959), who states, at p. 116: "Thus in considering the number of employees that might have been involved since 1822, 1898 and 1926 respectively for arsenic, creosote, and salt-peter, the number of skin cancer cases attributed to these agents is so small that there appears to be considerable doubt as to whether they even should be included in the table. However, they have been included for the following reasons: In the case of arsenic, we know that hundreds of thousands of workers must be potentially exposed to it in the smelting industries, so that less than 25 cases reported since 1822 seems remarkably low. Nevertheless arsenic has been left in the Table because it is known that medicinal overdosage with arsenic leads to hyperkeratoses of the palms and soles. These lesions are believed by practically all authorities to be precursors of cancer."

An illustration of an erroneous implication of arsenic cancer is given by Frost, "Considerations on the Reality of 'Arsenic' Cancer," cited at footnote 32, which was the belief that arsenic dust caused lung cancer in Schneeberg, Germany. Eventually, however, radiation injury from pitchblende was considered a more likely cause of the incidence of lung cancer. Dr. W. C. Hueper, of the National Cancer Institute, perhaps the most outspoken scientist who considers "arsenic and its compounds" (*Hearings before the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, House of Representatives* (1952), Pt. 3, p. 1366) as known carcinogenic agents, testified that "an appreciable number" of skin cancers were observed between 1938 and 1942 among vineyard workers in a district in Germany which had had an epidemic of chronic arsenic poisoning from the use of arsenical pesticides (pp. 1366-1367). Dr. Hueper repeated this testimony subsequently (*Hearings*, (1958), p. 372), and added: "Now they have among their vineyard workers not only skin cancer but lung cancer and liver cancers." However, Dr. Hueper's conclusion is purely speculative. Consider Eckardt, work cited above, at p. 147: "Thus, the fact that eight vineyard workers in Germany developed cancer of the lung, in itself, neither argues for nor against the idea that there is an occupational hazard of lung cancer among vineyard workers. It is necessary to know the number of vineyard workers involved, and determine whether the incidence is significantly elevated on a statistical basis. If one travels down the Rhine River in Germany, one is impressed with the vineyards which occupy the hills for mile upon mile of the trip. There must be thousands upon thousands of people who work in these vineyards, so that 8 lung cancers among them may well constitute only the anticipated incidence of this disease. These observations only suggest that additional studies such as those done by Roth be undertaken in an attempt to develop definitive answers."

evidence—as distinguished from speculation—involving inorganic arsenicals is that massive long-term potassium arsenite therapy—at a level high enough to constitute arsenic poisoning—produces a characteristic thickening of the skin of the palms of the hands and the soles of the feet and produces abnormal pigmentation of the skin. In about 20 per cent of the individuals developing skin-thickening, the patches of thickened skin became cancerous; this hardly constitutes reliable evidence of carcinogenicity of all arsenical compounds. It suggests only that arsenic poisoning by potassium arsenite, a highly toxic compound, may produce a condition which *in turn* may cause cancer.[35]

Nevertheless, according to the Food and Drug Administration, no food-additive regulation can be issued permitting the use of any compound containing arsenic, including organic arsenicals, until and unless the compound can be shown not to have any carcinogenic potential.[36] But scientists indicate that no one can show that any compound cannot cause cancer.[37] Thus, only those uses of organic

(Footnote 34 continued)

In fact, the United States Public Health Service conducted extensive studies, between 1937 and 1940, of orchardists around Wenatchee, Washington, where lead arsenate had been used as a tree spray since about 1900. No difference in incidence of various diseases, including cancer, was seen between orchardists and their families regularly exposed to unusual amounts of lead arsenate and those not so exposed (Frost, "Considerations on the Reality of 'Arsenic' Cancer," cited at footnote 32).

[35] *Hearings*, cited at footnote 4, at pp. 334-335 (testimony of Paul Gerden) and at p. 810 (testimony of Dr. Morton L. Levin); Frost, "Considerations on the Reality of 'Arsenic' Cancer," cited at footnote 32. Frost concluded: "Neubauer's (1947) major review *Arsenical Cancer* lists only 143 cases of medicinal 'arsenical' epithelioma from the literature. Thus 'arsenic' cancers appear as an extreme rarity, even from 1905-1947 when millions of people were treated with arsenicals. Cancer is reported to occur in one of five men and one of four women. Eckardt (1959) indicates that cancer of the skin occurs normally in about 30 per 100,000 per year. From the statistical standpoint the reported cases would actually seem far too isolated and few in number to warrant a direct association between arsenic therapy and cancer."

[36] The basic policy of the Food and Drug Administration applicable to veterinary drugs held to be carcinogens within the meaning of the Delaney clause is set forth in the regulations at 21 CFR Sec. 3.37 (see footnote 28). Organic arsenical compounds were held to fall within the Delaney clause. See *Food Chemical News* for June 22, 1959, and for July 13, 1959. The FDA position was expressed in letters which said in part: "It is a known fact that certain inorganic arsenic compounds and certain synthetic materials with hormone-like activity similar to dienestrol diacetate have been found to produce cancer in man. Because of this, our scientific advisers cannot say that arsenic compounds used in feed or dienstrol diacetate are safe until it is demonstrated that such compounds do not have this carcinogenic potential. They would have to have appropriate data to answer this question. Furthermore, if an arsenic compound, after study, is found not to produce cancer itself, we would need to know whether any residue it leaves in edible products of treated animals is the organic or inorganic form."

[37] It seems clear that negative results in animal testing are not considered proof of lack of carcinogenicity in humans (Food Protection Committee, Food and Nutrition Board, publication cited at footnote 31, at p. 21). See Matson, work cited at footnote 25, at pp. 77-78. The Delaney clause uses the phrase "found to induce cancer." Secretary Flemming testified that this phrase applied only to substances which had been "demonstrated" to induce cancer (*Hearings* cited at footnote 4, at p. 63). In testimony given prior to enactment of the food additives law, Dr. Herbert E. Carter stated (*Hearings*, (1958), p. 377): "It is commonplace for even a slight alteration in struc-

(Continued on next page)

arsenical compounds which are exempt from the food-additives law may be employed.

There is not one scintilla of evidence of cancer induction throughout history by any organic arsenical compound in man, however. No one has been able reliably to induce cancer with any organic arsenic compound in any species of animal at any level or by any means of administration.

The evidence is overwhelming, furthermore, that the organic arsenical compounds, which have been extensively tested and approved by the Food and Drug Administration, under the new-drug law, have been shown to be safe under their conditions of use.

Because of general recognition of safety of several of the organic arsenicals, in fact, they no longer require regulation under the new-drug law as new drugs and they are considered to be exempt from the food-additives law. In each case, however, all organic arsenical compounds were originally marketed pursuant to effective new-drug applications under the Federal Food, Drug and Cosmetic Act. Organic arsenicals have been used in human medicine since the beginning of the twentieth century and in medicated animal feed since 1951. Residues of the drugs in eggs and tissues, furthermore, when used under recommended conditions, are in the same range as normal content of arsenic in such foods. Approval of residues of organic arsenicals under these circumstances is in accordance with established policy of the Food and Drug Administration under the new-drug law. Such residues are less than established tolerances in fruits and vegetables sprayed with inorganic arsenicals, and are insignificant in relation to the natural background of arsenic.[38]

(Footnote 37 continued)
ture to change drastically the biological properties of a substance. Unfortunately each compound must be considered as an individual and evaluated independently." Accordingly, it seems improper to prohibit organic arsenicals with a long history of safe use on the basis of inconclusive evidence pertaining to inorganic arsenic compounds. *Hearings* cited at footnote 4, at pp. 335-341 (testimony of Paul Gerden).

[38] Tolerances for lead arsenic and calcium arsenate, inorganic arsenic products used on fruits and vegetables, are in effect under section 408 of the Federal Food, Drug, and Cosmetic Act, applicable to pesticide chemicals in or on raw agricultural commodities (21 CFR Sec. 120.101(e)). Dr. William J. Darby, chairman of the Food Protection Committee, testified (*Hearings* cited at footnote 4, at pp. 834-835): "You have heard that many substances which are naturally present in foodstuffs can, under special conditions, or conditions of very high intake, be associated with the occurrence of experimental cancer. To mention some of these which were noted yesterday, arsenic, selenium, radioactive materials, even lipids or fats, some precursors of oxyloc acid and so on. One could extend this list considerably. For example, one could even question whether the lowly turnip, and its several relatives, contain a substance which might be considered suspect—that is, a naturally occurring anti-thyroid substance, which has certain substances in common with aminotrizol. The content of foods vary greatly in all of these substances. I do not know, however, of any evidence which links the ingestion of these small amounts present in foods to cancer in the human. They are unavoidable, and any workable legislation

It is submitted that, in the case of organic arsenicals, the Delaney clause has again operated to deprive a safe use of these drugs from clearance in violation of the basic principle of the food-additives law. Scientific judgment has been entirely excluded not only in the evaluation of safety, but also in the evaluation of whether or not these compounds are even capable of causing cancer.[39]

Current Status—Cost of Delaney Clause

The cost of the Delaney clause to our growing society could prove enormous. It is purely conjectural whether a single human cancer will have been prevented by this action,[40] but there is little question about its likely consequences to feed technology and, ultimately, to the public health.

The chief cost is not the potential loss of any single product to society, although the loss of any valuable product is to be deplored. If diethylstilbestrol and organic arsenicals were to be banned from the market, our farmers would have to produce significantly more animals each year to obtain the same amount of food products that we can now produce with the aid of these drugs.[41] I have said that existing uses of diethylstilbestrol and organic arsenicals are exempt from the food-additives law. But the use of diethylstilbestrol for implantation in poultry for the purpose of synthetic caponization was also exempt from the food-additives law. That use of the diethylstilbestrol has already been suspended because of the pervasive influence of the

(Footnote 38 continued)
must allow the decision by someone that this is the case." For organic arsenicals, see references cited at footnote 32, and *Hearings* cited at footnote 4, at p. 336 (testimony of Paul Gerden).

[39] The operation of the Delaney clause to cover dubious cases of carcinogenicity is a defect of the clause that was pointed out by the great majority of the scientists appearing April 5-6, 1960, before the Committee on Interstate and Foreign Commerce (*Hearings* cited at footnote 4, at pp. 685-889). The tendency to consider compounds as potential carcinogens unless proven noncarcinogenic is an aspect of repudiation of scientific judgment. Thus, Dr. Harold L. Stewart proposed not only that the Delaney clause be retained *in toto*, but also that exhaustive tests be required for each compound to minimize the possibility that it might be carcinogenic (*Hearings* cited at footnote 4, at pp. 703-708). But the cost of such testing for one compound was estimated to be as much as $200,000 (*Hearings* cited at footnote 4, at p. 752). Furthermore, such research is considered nonproductive, scientifically. *Hearings* cited at footnote 4, at pp. 825-826.

[40] There was testimony offered before Congress at the time the food additives bill was being considered that there was no single proven instance of any human cancer related to a food additive. Dr. John H. Folger (*Hearings*, (1958), p. 363), and Dr. Emerson Day (*Hearings*, (1958), p. 374) so testified. More recently, Dr. William J. Darby, Chairman of the Food Protection Committee, offered similar testimony (*Hearings* cited at footnote 4, at pp. 834-835). Dr. M. R. Zavon pointed out that if food additives were a significant problem in causation of cancer, one would not expect to find a decrease in incidence of cancer of the stomach. Yet such has occurred (*Hearings* cited at footnote 4, at p. 825).

[41] See, for example, *Hearings* cited at footnote 4, at p. 462 (testimony of Dr. Thomas Carney).

Delaney clause.[42] Other uses of that drug and the uses of organic arsenicals must be considered as threatened as long as the flat ban of the Delaney clause can be made to apply to them.

Threat to Progress

The chief cost, however, is the threat to future progress based on research. There is evidence that research projects have already been curtailed and that potential research projects are now being tabled in veterinary medicine.[43] These decisions of management to shift research effort elsewhere have been taken because the tremendous expense which is involved in the development of new veterinary drugs for use in medicated feeds may not be justified under present conditions.

There are several factors which have operated to influence industry in this regard. On the one hand there is the uncertain operation of the Delaney clause. Lack of scientific agreement as to the definition of a "carcinogen" or as to the tests which will be considered sufficient to establish noncarcinogenicity, coupled with the enormous expense involved in testing new drugs, are part of the reason.[44] On the other hand, there are some interpretations of the food-additives law already advanced by the Food and Drug Administration which seem to be applicable primarily to veterinary drugs and which make costs of develop-

[42] See Goodrich, "Cranberries, Chickens and Charcoal," 15 *Food Drug Cosmetic Law Journal* 87 (February, 1960). Since 1947, there has been a practice to implant pellets of diethylstilbestrol in poultry at the base of the skull for the purpose of synthetic caponization. New drug applications were made effective clearing this use of the drug on the basis of evidence that only a minute amount of residue of the drug would remain in the tissues of treated birds at the time of slaughter. In 1957 the actual residues were calculated, and found to be minute. In December, 1959, however, Secretary Flemming saw fit to announce publicly that the principle of the Delaney clause was the basis for requesting immediate suspension of the sale of diethylstilbestrol for use in poultry and immediate suspension of the sale of treated birds. Though the Secretary reported that voluntary compliance with his request had been obtained, that only 1 per cent of the chickens on the market were affected, and that consumers can buy poultry with full confidence that it is safe and wholesome, nevertheless, the incident was bound to reduce confidence of the public in our food supply.

[43] Hagan, work cited at footnote 22: *Hearings* cited at footnote 4, at pp. 465-467 (testimony of Dr. Thomas Carney); *Chemical and Engineering News*, March 21, 1960, p. 19.

[44] The panel of scientists which convened on April 5-6, 1960 (*Hearings* cited at footnote 4, at pp. 685-889) revealed basic differences of opinion on such vital matters as which substances are carcinogens and what tests might be considered appropriate to establish either carcinogenicity or noncarcinogenicity. At one point Dr. G. Burroughs Mide admitted it was theoretically possible to ban salt under the Delaney clause. Dr. Morton L. Levin thought we should not exclude the possibility that commonly occurring substances might in fact be carcinogenic for humans. Roasted coffee beans contain minute amounts of a strong carcinogen, according to Dr. James A. Miller. The philosophy of the Delaney clause, pushed to extremes, would require us all to wear lead armor, to live a subterrestrial existence, to breathe especially filtered and treated air, to drink especially treated water, to refrain from drinking coffee, tea, or eating any foods processed by roasting or smoking, or from consuming most naturally occurring foods, according to Dr. William J. Darby. It is likely that food additives would largely be suspect under the Delaney clause.

ment in relation to possible markets virtually prohibitive.[45] The scope of the exemptions from the food-additives law which are to be accorded to existing medicated feeds are so narrow that supposedly exempt drugs are no longer exempt from the food-additives law when mixed with new drugs in medicated feeds. Therefore, the manufacturer of a new drug is required to obtain a food-additive regulation not only for his own drug, but also for every existing drug with which his drug will be mixed—all at enormous expense. The market for the new drug, however, will probably be very small, indeed, because the Delaney clause will prohibit issuance of a regulation for a new drug added to any existing medicated feed containing diethylstilbestrol or an arsenical.

The cost of the Delaney clause is certainly going to be high. Can our society afford to pay the price?

Fundamental Defect—Conflicting Policies

Let us now consider how to restore scientific judgment to the evaluation of food and drugs in a framework which provides maximum public-health protection.

In my opinion, the problem is not basically the administration of the law. In the past, we have been able to work out problems of administrative interpretation with the Food and Drug Administration on a scientific basis, and we can probably continue to do so in the future.[46]

The basic problem, rather, in my opinion, is legislative. It seems reasonably clear, as previously mentioned, that Congress intended to establish the basic principle that additives whose uses are shown to be safe should be approved for such uses. The policy of the law is

[45] Sec. 201(s) of the Federal Food, Drug, and Cosmetic Act defines the term "food additive." The general language is broad enough to include a veterinary drug which is also a new drug pursuant to Sec. 201(p) of the Act. But Sec. 201(s) contains a clause specifically excluding any substance used in accordance with a sanction or approval granted prior to September 6, 1958, under certain statutes, including the Federal Food, Drug, and Cosmetic Act, from the term "food additive." In the case of veterinary drugs which may also be food additives this exemption calls for interpretation. An effective new-drug application under Sec. 505 of the Act is certainly a prior sanction. But under Sec. 505, a new-drug application is effective only for the manufacturer who obtained it and for the particular conditions of use contained therein. Is the exemption of the drug from the food additives law also so limited? The Food and Drug Administration has argued that it is. Sec. 201(s) also excludes from the term "food additive" any substance which is generally recognized by qualified experts to be safe under the conditions of its intended use. FDA contends that this exemption, like the prior sanction exemption, is limited and does not apply to the drug when it is mixed in feed with a newly developed medication. Thus, the same drug may be both exempt and not exempt from the food-additives law at the same time and for the same use. See Hagan, work cited at footnote 22, and other references contained in footnotes 22-23.

[46] As a caveat, however, this is not to be construed as an implied agreement with the interpretations of the food additives law by the Food and Drug Administration.

stated to advance food technology as well as to protect the consumer. The trouble is that, by inserting the Delaney clause into the food-additives bill, Congress was—perhaps inadvertently—modifying that policy. As a result of the Delaney clause, in the case of compounds which are suspect as carcinogens under special conditions, manufacturers are not legally permitted to show that such a compound is safe under conditions of use.[47] Inquiry into the actual hazard from the use of the compound is absolutely foreclosed. The law itself makes a prejudgment that safe use of the compound cannot be established.

Now Congress has decided that food technology should be advanced. This is a value judgment. It was a decision that followed eight years of consideration; numerous hearings; a wealth of articles; and much debate. In order to accomplish this policy, however, it was deemed necessary to abandon the long-standing per se prohibition against the addition of poisonous or deleterious substances to food. This necessarily meant that Congress was willing to sanction the use of compounds which might be harmful under unusual conditions or in large quantities, but would be beneficial when used under controlled conditions. As a matter of established fact, it is not possible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any substance under every conceivable condition. However, through the application of scientific judgment, it was concluded that the health of consumers could be protected.[48]

Scientific judgment, however, is in essence the combination of research over a reasonably short period of time with insight as to the

[47] Dr. Morton L. Levin, who accepts the Delaney clause, with some latitude, however, in "exceptional circumstances," conceded that this means he would "accept false positives" and knowingly "exclude possibly harmless chemicals from our diet" (*Hearings* cited at footnote 4, at pp. 800-802.) This is the necessary effect of the Delaney clause. It is a departure from the announced purposes of the food-additives legislation.

[48] Congress rejected the philosophy (except to the degree the Delaney clause restores the *per se* prohibition of chemicals) of the food faddist who is not willing to accept scientific judgment in the evaluation of food additives. Examples of the food-faddist approach are contained in footnote 30. The food faddists were a factor in inducing Congress to institute the food-additives investigation that got under way in 1950, according to the former head of the Food and Drug Administration. Dunbar, "Chemical Additives in Food," 6 *Food Drug Cosmetic Law Journal* 431 (1951). They were a factor in the pressure which was exerted to enact the Delaney clause and they are now active in order to maintain the integrity of the clause against efforts to restore the basic philosophy of the food-additives law. Matson, *Scientific Judgment in Law and Regulation*, work cited at footnote 25, at pp. 73-76. More recently, Representative David S. King, of Utah, read into the record of the Interstate and Foreign Commerce Committee a letter from Geoffrey Martin, M. D., who wrote: "The Delaney Amendment in effect defends one small area of consumer protection which previously was defended by the *per se* principle." *Hearings* cited at footnote 4, at p. 414. See footnote 20 for the legislative history of the food-additives bill.

probable significance of the results.[49] The scientific method requires that a determination of safety must be independently made for each proposed use of a compound. By freezing present scientific knowledge into law and by prejudging an unknown number of compounds we *necessarily* depart from the scientific method, yet there is no reliable evidence that I can find that the Food and Drug Administration cannot make a judgment in each case which is consistent with the public welfare.[50]

Commissioner of Food and Drugs George P. Larrick had no doubt about the capacity of the Food and Drug Administration when he opposed the concept of the Delaney clause in testimony before the House Committee on Interstate and Foreign Commerce in 1957. He said then:

> But we see no more reason to single out cancer production for specific mention in the legislation than to single out production of high blood pressure, destruction of the blood-forming elements of the body, or production of nephritis, diabetes, or a host of other disorders. All of these things are of extreme importance. We, certainly, do not intend to sanction a chemical additive in the food supply unless the evidence rules out any reasonable ground for believing that the proposed use will constitute a hazard to the public health in any respect.[51]

The panel of eminent scientists who were called upon in 1957 to advise the House Committee on Interstate and Foreign Commerce stressed the individuality of each analysis of safety. Summarizing the individual statements of the scientists, Dr. W. J. Darby, of Vanderbilt University, said:

> It was repeatedly emphasized by the participants that each additive, each chemical additive, is a different substance, and, therefore, it presents certain differences in judging the results of testing and in expressing judgment on the safety for the particular use or uses for which this additive is proposed.
>
> It would seem that in any regulatory procedure there should be an allowance for what we might call individuality of additives—individual appraisal of safety.[52]

Nevertheless, the Delaney clause was incorporated into the food-additives bill after the bill had been reported by the House Committee on Interstate and Foreign Commerce without any cancer clause. The chairman of the committee reported to Congress that the clause had been requested by Congressman Delaney. Congressman Delaney stated that the clause followed the recommendation of the

---

[49] See footnote 25.

[50] In fact, a number of the scientists testifying before the Committee on Interstate and Foreign Commerce on April 5-6, 1960, indicated confidence in the ability of the Food and Drug Administration to exercise judgment. *Hearings* cited at footnote 4, at p. 875 (Dr. Paul Cannon); p. 886 (Dr. William J. Darby); p. 743 (Dr. Charles J. Kensler); pp. 723-724 (Dr. Walter S. O'Donnell); p. 825 (Dr. Mitchell Zavon).

[51] *Hearings* (1958), p. 454.

[52] *Hearings* (1958), p. 353.

symposium of the international union against cancer, held in Rome in 1956, and discussions he had had with several cancer researchers. There was very little discussion of the potential effect of this clause on the legislation, but there is some evidence that the Delaney clause was not thought to alter the basic philosophy of the bill.[53]

In fact, the Senate Committee on Labor and Public Welfare reported:

> In short, we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration.[54]

This statement was a monumental miscalculation.

The Delaney clause, clearly, departs from the philosophy of the food-additives law. Its standard of prejudgment reflects the views of some, but not all, cancer researchers, whose experience does not reach into the broader areas of public welfare and who are impressed mostly with their lack of knowledge of the factors responsible for cancer incidence. Faced with such lack of knowledge, their remedy is to repudiate scientific judgment altogether, yet it is generally accepted that thresholds do exist for cancer-causing compounds as for other compounds and that in doubtful cases, at least, safe tolerances can be set.[55]

Those scientists who take into account the broader aspects of public health, however, have expressed the opinion that the Delaney clause should be modified or entirely deleted. Thus, summarizing the views of several of the members of a scientific panel that appeared before the Committee on Interstate and Foreign Commerce a few days ago, Dr. William J. Darby, chairman of the Food Protection Committee and chairman of the panel, said: "It was indicated yesterday that full protection of the public would be provided without a

---

[53] The legislative history of the Delaney clause is extensively reviewed by Edward Brown Williams in *Hearings* cited at footnote 4, at pp. 518-542.

[54] S. Rept. 2422, 85th Cong., 2d Sess., Committee on Labor and Public Welfare, United States Senate, August 18, 1958.

[55] Dr. Zavon said (*Hearings* cited at footnote 4, at p. 825): "Most of the fears conjured up with regard to cancer are to the effect that we don't know, therefore, it might cause cancer. Therefore, we can't take a chance." As to the existence of thresholds, see Food Protection Committee, Food and Nutrition Board, publication cited at footnote 31, at pp. 31-33. Nearly all the scientists testifying before the Committee on Interstate and Foreign Commerce on April 5-6, 1960, were willing to set tolerances for exceptional or doubtful compounds that might conceivably come under the Delaney clause (*Hearings* cited at footnote 4, at p. 874 (Dr. Charles J. Kensler); p. 875 (Dr. Paul Cannon); p. 879 (Dr. Floyd DeEds); p. 881 (Dr. Morton L. Levin); p. 883 (Dr. James A. Miller); p. 883 (Dr. Albert Tannenbaum); p. 884 (Dr. Mitchell Zavon); p. 885 (Dr. William J. Darby); p. 722 (Dr. Walter S. O'Donnell)).

specific cancer clause." [56] Dr. Darby indicated that this was also his personal opinion.

The conflict in policy created by the Delaney clause was pinpointed by Dr. M. R. Zavon, of Kettering Laboratory of Industrial Health, who told the committee:

> . . . the proper question in 1960 is first to determine what is the ultimate object of our food protection laws?
>
> Is it to protect our population against any conceivable hazard or is it to assure the greatest measure of good to the greatest possible number with a minimum of possible harm to the least number?[57]

Answering this question, Dr. Zavon said:

> The object is the maximum well being of our population. There is a serious question in my mind whether the Delaney clause will not cause great disruption of the type of research which has gone so far to improve the well-being of our population.[58]

Responsibility of Congress

The responsibility of Congress in this situation seems clear. The establishment of policy is the essence of the legislative function.[59] No administrative agency, subject as it is to many pressures, can consistently administer a law whose policies are in conflict.

We may properly expect Congress to determine the policy of the law, and Congress must accept responsibility for the decision which it reaches. Once the facts are obtained, Congress must decide which of the several courses of action serves the total public welfare best.

It is submitted that the basic policy of the law has already been determined—to achieve maximum well-being by advancing food technology as well as by protecting the consumer from harm through the application of scientific judgment. As written, the Delaney clause precludes scientific judgment and frustrates the basic policy of the law. It is imperative that to achieve the maximum well-being of our nation, the Delaney clause must be eliminated or amended so as to permit the use of safe compounds.

Congress is now considering the Delaney clause. The forum is the House Committee on Interstate and Foreign Commerce. The subject is color additives. But it is the food-additives law which is

---

[56] *Hearings*, (1960), p. 836.
[57] *Hearings*, (1960), pp. 821-822.
[58] *Hearings*, (1960), p. 827.
[59] *Mutual Film Corporation v. International Commission of Ohio*, 236 U. S. 230 (1915); *Panama Refining Company v. Ryan*, 293 U. S. 388 (1935); *Opp Cotton Mills, Inc. v. Administrator of Wage and Hour Division*, 312 U. S. 126 (1941).

actually on trial. This matter should receive serious attention from the animal-health industry, for the decision which Congress will make will be based upon the information with which its members have been supplied.

We of the Animal Health Institute are deeply concerned with the public health. My company would not think of marketing any drug which is likely to cause harm. But we don't think the public welfare is served in the twentieth century by abandoning scientific and technological progress which has given this nation the highest standard of living in the world. **[The End]**

FTC ISSUES ADVERTISING GUIDES FOR "GUARANTEES"

Guides designed to eliminate misleading "guarantee" claims in advertising have been issued by the Federal Trade Commission. They cover the major principles governing the advertising of guarantees, warranties, purported guarantees and warranties, and any promise or representation in the nature of a guarantee or warranty.

The guides, adopted by the Commission on April 26 and issued the following day, make it clear that, in general, any guarantee in advertising shall clearly and conspicuously disclose the nature and extent of the guarantee, the manner in which the guarantor will perform, and the identity of the guarantor.

Many guarantees are adjusted by the guarantor on a pro-rata basis. The advertising of these guarantees should clearly disclose this fact, and the basis on which they will be prorated—for example, the time for which the guaranteed product has been used, and the manner in which the guarantor will perform. If these guarantees are to be adjusted on the basis of a price other than that paid by the purchaser, this price should be clearly and conspicuously disclosed. (Guarantees which provide for an adjustment based on a fictitious list price should not be used even where adequate disclosure of the price used is made.)

"Satisfaction or your money back," "ten-day free trial," or similar representations will be construed as a guarantee that the full purchase price will be refunded at the option of the purchaser.

If the words "life," "lifetime," or the like, are used in advertising to show the duration of a guarantee, and they relate to any life other than that of the purchaser or original user, the "life" referred to shall be clearly and conspicuously disclosed.

Advertisements frequently contain representations of guarantees that assure prospective purchasers that savings may be realized in the purchase of the advertiser's products. These should include a clear and conspicuous disclosure of what the guarantor will do if the savings are not realized, together with any time or other limitations that he may impose.

Others of the guides deal with guarantees under which the guarantor does not or cannot perform and with guarantees as misrepresentation.

The Scientists' Forum

By BERNARD L. OSER

President and Director, Food and Drug Research Laboratories, Inc.

THE following list of food chemicals is a composite of several lists promulgated up to March, 1960, by the Commissioner of Food and Drugs, comprising substances employed in food production, processing, or packaging which are either (1) generally recognized as safe ("GRAS") when used for the purposes indicated or (2) have been sanctioned for specified uses prior to the enactment of the food-additives amendment of 1958. In the sense of the legal definition of the Federal Food, Drug, and Cosmetic Act, substances in these categories are not considered to be "food additives." It is required that they be of "appropriate food grade" (and prepared and handled as food ingredients) or, in the case of packaging components, of "good commercial grade." Furthermore, the quantity of a substance that becomes a component of food as a result of its use in the manufacture, processing or packaging of food must not exceed the minimum quantity reasonably required to accomplish its effect. In some cases these limits are specified.

Because of the impracticability of listing all substances for which prior sanctions or approvals have been granted or which are generally recognized as safe by appropriately qualified scientists, many substances that fit into these classifications may not be "white-listed."

The composite list here presented does not include substances for which time extensions have been granted under the Act nor those for which petitions have been filed or regulations issued. It does, however, include substances (indicated by asterisks) listed in proposed orders of the Commissioner (published in the *Federal Register* February 2 and March 1, 1960) which had not become final as of March, 1960.

Whereas numerous lists of substances have been published in the *Federal Register* for which time extensions have been granted, no

additions to the "'white list" have appeared up to the present writing (May 12, 1960).

Composite Food-Additive "White List"

Substance	Limitations
ANTICAKING AGENTS	
Aluminum calcium silicate	2% in table salt
Calcium silicate	5% in baking powder
Calcium silicate	2% in table salt
Magnesium silicate	2% in table salt
Sodium aluminosilicate *	2%
Sodium calcium aluminosilicate, hydrated *	2%
Tricalcium silicate	2% in table salt
BUFFERS AND NEUTRALIZING AGENTS	
Acetic acid	
Adipic acid *	
Aluminum ammonium sulfate	
Aluminum potassium sulfate	
Aluminum sodium sulfate	
Ammonium bicarbonate	
Ammonium carbonate	
Ammonium hydroxide	
Ammonium phosphate (mono- and di-basic-)	
Calcium carbonate	
Calcium chloride	
Calcium citrate	
Calcium gluconate	
Calcium hydroxide	
Calcium lactate	
Calcium oxide	
Calcium phosphate	
Citric acid	
Hydrochloric acid *	
Lactic acid	
Magnesium carbonate	
Magnesium oxide	
Malic acid *	
Phosphoric acid *	
Potassium acid tartrate	
Potassium bicarbonate	
Potassium carbonate	
Potassium citrate	
Potassium hydroxide	
Sodium acetate	
Sodium acid pyrophosphate	
Sodium aluminum phosphate	
Sodium bicarbonate	
Sodium carbonate	
Sodium citrate	
Sodium hydroxide	
Sodium phosphate (mono-, di-, tri-)	
Sodium potassium tartrate	
Sodium sesquicarbonate	
Succinic acid *	
Sulfuric acid	
Tartaric acid	
CHEMICAL PRESERVATIVES	
Ascorbic acid	
Ascorbyl palmitate	
Benzoic acid	0.1%

Substance	Limitations
Butylated hydroxyanisole	See note (a), page 351
Butylated hydroxytoluene	See note (a), page 351
Calcium ascorbate	
Calcium propionate	
Calcium sorbate *	
Caprylic acid	In cheese wraps
Dilauryl thiodipropionate	See note (a), page 351
Erythorbic acid	
Gum guaiac	0.1% (equivalent antioxidant activity 0.01%). In edible fats or oils
Methylparaben (methyl-p-hydroxybenzoate) *	0.1%
Nordihydroguaiaretic acid	See note (a), page 351
Potassium bisulfite	See note (b), page 351
Potassium metabisulfite	See note (b), page 351
Potassium sorbate	
Propionic acid	
Propyl gallate	See note (a), page 351
Propylparaben (propyl-p-hydroxybenzoate) *	0.1%
Sodium ascorbate	
Sodium benzoate	0.1%
Sodium bisulfite	See note (b), page 351
Sodium metabisulfite	See note (b), page 351
Sodium propionate	
Sodium sorbate	
Sodium sulfite	See note (b), page 351
Sorbic acid	
Stannous chloride *	0.0015% calculated as tin
Sulfur dioxide	See note (b), page 351
Thiodipropionic acid	See note (a), page 351
Tocopherols	
EMULSIFYING AGENTS	
Cholic acid	0.1% Dried egg whites
Desoxycholic acid	0.1% Dried egg whites
Diacetyl tartaric acid esters of mono- and diglycerides from the glycerolysis of edible fats or oils	
Glycocholic acid	0.1% Dried egg whites
Mono- and diglycerides from the glycerolysis of edible fats or oils	
Monosodium phosphate derivatives of mono- and diglycerides from the glycerolysis of edible fats or oils	
Ox bile extract	0.1% Dried egg whites
Propylene glycol	
Taurocholic acid (or its sodium salt)	0.1% Dried egg whites

Substances	
FLAVORING AND SEASONING	
SPICES AND OTHER NATURAL SEASONINGS AND FLAVORINGS (Leaves, Roots, Barks, Berries, etc.)	
Allspice	Capsicum
Anise	Caraway
Anise, star	Caraway, black (black cumin)
Basil, bush	Cardamom (cardamon)
Basil, sweet	Cassia, Chinese
Bay	Cassia, Padang or Batavia
Calendula	Cassia, Saigon
Capers	Cayenne pepper

Substances

FLAVORING AND SEASONING (Continued)

SPICES AND OTHER NATURAL SEASONINGS AND FLAVORINGS (Continued)

Celery seed
Chives
Cinnamon, Ceylon
Cinnamon, Chinese
Cinnamon, Saigon
Clary (clary sage)
Cloves
Coriander
Cumin (cummin)
Cumin, black (black caraway)
Dill
Fennel, common
Fennel, sweet (finocchio, Florence fennel)
Fenugreek
Garlic
Ginger
Glycyrrhiza
Grains of paradise
Horseradish
Lavender
Licorice
Mace
Marigold, pot
Marjoram, pot
Marjoram, sweet
Mustard, black or brown
Mustard, brown
Mustard, white or yellow
Nutmeg
Oregano (oreganum, Mexican oregano, Mexican sage, origan)
Paprika
Parsley
Pepper, black
Pepper, cayenne
Pepper, red
Pepper, white
Peppermint
Poppy seed
Pot marigold
Pot marjoram
Rosemary
Rue
Saffron
Sage
Savory, summer
Savory, winter
Sesame
Spearmint
Star anise
Tarragon
Thyme
Turmeric
Vanilla
Zedoary

ESSENTIAL OILS, OLEORESINS (Solvent-free) and natural extractives (including distillates)

Allspice (oil)
Almond, bitter (free from prussic acid) (oil)
Angelica root (oil)
Angelica seed (oil)
Angelica stem (oil)
Angostura (cusparia bark) (oil)
Anise (oil)
Asafetida (oil)
Balsam of Peru (oil)
Basil (oil)
Bay leaves (oil)
Bay (myrcia oil) (oil)
Bitter almond (free from prussic acid) (oil)
Bois de rose (oil)
Cananga (oil)
Capsicum (oil)
Caraway (oil)
Cardamon seed (cardamon) (oil)
Carob bean (oil)
Cascarilla bark (oil)
Cassia bark, Chinese (oil)
Cassia bark, Padang or Batavia (oil)
Cassia bark, Saigon (oil)
Celery seed (oil)
Chamomile flowers, Hungarian (camomile) (oil)
Chamomile flowers, Roman or English (camomile) (oil)
Cherry, wild, bark (oil)
Chicory (oil)
Cinnamon bark, Ceylon (oil)
Cinnamon bark, Chinese (oil)
Cinnamon bark, Saigon (oil)
Cinnamon leaf, Ceylon (oil)
Cinnamon leaf, Chinese (oil)
Cinnamon leaf, Saigon (oil)
Citronella (oil)
Citrus peels (oil)
Clary (clary sage) (oil)
Clove bud (oil)
Clove leaf (oil)
Clove stem (oil)
Coca (decocainized) (oil)
Coffee (oil)
Cola nut (oil)
Coriander (oil)
Cumin (cummin) (oil)
Cusparia bark (oil)
Dill (oil)
Estragole (esdragol, esdragon, tarragon) (oil)
Fennel, sweet (oil)
Fenugreek (oil)
Garlic (oil)
Geranium, East Indian (oil)
Geranium, rose (oil)
Ginger (oil)
Glycyrrhiza (oil)
Grapefruit (oil)
Guava (oil)
Hoarhound (oil)
Hops (oil)
Jasmine (oil)

Substances	
Juniper (berries) (oil)	Pimenta (oil)
Kola nut (oil)	Pimenta leaf (oil)
Laurel leaves (oil)	Pipsissewa leaves (oil)
Lavender (oil)	Pomegranate (oil)
Lavender, spike (oil)	Prickly ash bark (oil)
Lavandin (oil)	Rose absolute (oil)
Lemon (oil)	Rose (otto of roses, attar of roses) (oil)
Lemon grass (oil)	Rose geranium (oil)
Licorice (oil)	Rosemary (oil)
Lime (oil)	Rue (oil)
Locust bean (oil)	Saffron (oil)
Mace (oil)	Sage (oil)
Mandarin (oil)	Sage, Spanish (oil)
Marjoram, sweet (oil)	St. John's Bread (oil)
Maté (oil)	Schinus molle (oil)
Mustard (oil)	Spanish sage (oil)
Naringin (oil)	Spearmint (oil)
Neroli, bigarade (oil)	Spike lavender (oil)
Nutmeg (oil)	Tangerine (oil)
Onion (oil)	Tarragon (oil)
Orange, bitter, flowers (oil)	Tea (oil)
Orange leaf (oil)	Thyme (oil)
Orange, bitter, peel (oil)	Thyme, white (oil)
Orange, sweet (oil)	Tuberose (oil)
Origanum (oil)	Turmeric (oil)
Palmarosa (oil)	Vanilla (oil)
Paprika (oil)	Violet leaves absolute (oil)
Parsley (oil)	Wild cherry bark (oil)
Pepper, black (oil)	Ylang-ylang (oil)
Pepper, white (oil)	Zedoary bark (oil)
Peppermint (oil)	
Peruvian balsam (oil)	MISCELLANEOUS
Petitgrain (oil)	Civet (zibeth, zibet, zibetum)
Petitgrain lemon (oil)	Cognac oil, white and green
Petitgrain mandarin or tangerine (oil)	Musk (Tonquin musk)

Substance	Limitations
NUTRIENTS	
Ascorbic acid	
Calcium carbonate	
Calcium oxide	
Calcium pantothenate	
Calcium phosphate (mono-, di-, tribasic)	
Calcium sulfate	
Carotene	
Choline bitartrate *	
Copper gluconate	0.005%
Cuprous iodide	0.01% in table salt as a source of dietary iodine
Ferric phosphate	
Ferric pyrophosphate	
Ferric sodium pyrophosphate	
Ferrous sulfate	
Glycine (aminoacetic acid) *	Animal feeds
Inositol *	
Iron, reduced	
1-Lysine monohydrochloride	
Methionine *	Animal feeds
Methionine hydroxy analog and its salts *	Animal feeds
Niacin	
Niacinamide	
D-Pantothenyl alcohol	
Potassium chloride	
Potassium iodide	0.01% in table salt as a source of dietary iodine

Substance	Limitations
NUTRIENTS (Continued)	
Pyridoxine hydrochloride	
Riboflavin	
Riboflavin-5-phosphate	
Sodium pantothenate	
Sodium phosphate (mono-, di-, tribasic)	
Thiamine hydrochloride	
Thiamine mononitrate	
Tocopherols	
a-Tocopherol acetate	
Vitamin A	
Vitamin A acetate	
Vitamin A palmitate	
Vitamin B_{12}	
Vitamin D_2	
Vitamin D_3	
PACKAGING MATERIALS **(See also Paper and Paperboard)**	
ANTIOXIDANTS	
Butylated hydroxyanisole	0.005%
Butylated hydroxytoluene	0.005%
Dilauryl thiodipropionate	0.005%
Distearyl thiodipropionate	0.005%
Gum guaiac	0.005%
Nordihydroguaiaretic acid	0.005%
Propyl gallate	0.005%
Thiodipropionic acid	0.005%
2, 4, 5-Trihydroxy butyrophenone	0.005%
ANTIMYCOTICS	
Calcium propionate	
Methylparaben (methyl p-hydroxy-benzoate)	
Propylparaben (propyl p-hydroxy-benzoate)	
Sodium benzoate	
Sodium propionate	
Sorbic acid	
DRIERS	
Cobalt caprylate	
Cobalt linoleate	
Cobalt naphthenate	
Cobalt tallate	
Iron caprylate	
Iron linoleate	
Iron naphthenate	
Iron tallate	
Manganese caprylate	
Manganese linoleate	
Manganese naphthenate	
Manganese tallate	
DRYING OILS	
Chinawood oil (tung oil)	as components of finished resins
Dehydrated castor oil	as components of finished resins
Linseed oil	as components of finished resins
Tall oil	as components of finished resins
PLASTICIZERS	
Acetyl tributyl citrate	
Acetyl triethyl citrate	
p-tert-Butylphenyl salicylate	
Butyl stearate	
Butylphthalyl butyl glycolate	
Dibutyl sebacate	
Diethyl phthalate	
Diisobutyl adipate	
Diisooctyl phthalate	For foods of high water content only

Substances	Limitations
Diphenyl-2-ethylhexyl phosphate	
di-(2-Ethylhexyl) phthalate	For foods of high water content only
Epoxidized soybean oil	See note (f), page 351
Ethylphthalyl ethyl glycolate	
Glycerol monooleate	
Monoisopropyl citrate	
Mono, di-, and tristearyl citrate	
Triacetin (glycerol triacetate)	
Triethyl citrate	
3-(2-Xenoyl)-1, 2-epoxypropane	
RELEASE AGENTS	
Dimethylpolysiloxane	See note (g), page 351
Linoleamide (linoleic acid amide)	
Oleamide (oleic acid amide)	
Palmitamide (palmitic acid amide)	
Polyethylene glycol 400	
Polyethylene glycol 1500	
Polyethylene glycol 4000	
Stearamide (stearic acid amide)	
STABILIZERS	
Aluminum mono-, di-, and tristearate	
Ammonium citrate	
Ammonium potassium hydrogen phosphate	
Calcium acetate	
Calcium carbonate	
Calcium glycerophosphate	
Calcium phosphate	
Calcium hydrogen phosphate	
Calcium oleate	
Calcium ricinoleate	
Calcium stearate	
Disodium hydrogen phosphate	
Magnesium glycerophosphate	
Magnesium stearate	
Magnesium phosphate	
Magnesium hydrogen phosphate	
Mono-, di-, and trisodium citrate	
Mono-, di-, and tripotassium citrate	
Potassium oleate	
Potassium stearate	
Sodium pyrophosphate	
Sodium stearate	
Sodium tetrapyrophosphate	
Tin stearate	Not to exceed 50 ppm tin as a migrant in finished food
Zinc orthophosphate	Not to exceed 50 ppm zinc as a migrant in finished food
Zinc resinate	Not to exceed 50 ppm zinc as a migrant in finished food
PAPER AND PAPERBOARD (note (h))	
Aliphatic polyoxyethylene ethers	See note (i), page 351
1-Alkyl (C_6-C_{18})-amino-3-propane monoacetate	See note (i), page 351
Aluminum hydroxide *	
Aluminum oleate *	
Alumium palmitate *	
Ammonium chloride *	
Borax	In adhesives, sizes, coatings. See note (i), page 351
Boric acid	Same as Borax
Butadiene-styrene copolymer	
Calcium sulfate *	
Casein *	

Substance	Limitations
PAPER AND PAPERBOARD (note (h)) (Continued)	
Cellulose acetate *	
Chromium complex of perfluoro-octane sulfonyl glycine	Waxed paper or paperboard. See note (i), page 351
Clay (kaolin) *	
Copper sulfate *	
Cornstarch *	
Corn sugar (sirup) *	
Dextrin *	
Diatomaceous earth filler *	
Disodium cyanodithioimido-carbamate with ethylenediamine and potassium N-dithiocarbamate and/or sodium 2-mercaptobenzothiazole	Slimicide. See note (i), page 351
Ethyl acrylate	
Ethyl acrylate and methyl methacrylate copolymers of itaconic or methacrylic acid	Waxed paper or paperboard. See note (i), page 351
Ethyl cellulose *	
Ethyl vanillin *	
Ferric sulfate*	
Ferrous sulfate*	
Formic acid*	
Hexamethylene tetramine	Setting agent for protein, including casein. See note (i), page 351
1-(2-Hydroxyethyl)-1-(4-chlorobutyl)-2-alkyl (C_8-C_{17}) imidazolinium chloride	
Invert sugar*	
Iron, reduced*	
Iron oxides*	
Itaconic acid (polymerized)	
Magnesium chloride*	
Magnesium sulfate*	
Melamine formaldehyde polymer	
Methyl acrylate (also polymerized)	
Methyl ethers of mono-, di-, and tripropylene glycol	See note (i), page 351
Myristo chromic chloride complex	
Nitrocellulose	
Oleic acid*	
Polyethylene glycol 400	
Polyvinyl acetate	
Polyvinyl alcohol (high or low viscosity) resins	Fatty foods only
Potassium pentachlorophenate	Slime control agent. See note (i), page 351
Potassium trichlorophenate	Slime control agent. See note (i), page 351
Propionic acid*	
α-Protein*	
Pulps*	From wood, straw, bagasse or other natural sources
Pyrethrins with piperonyl butoxide	In outside plies of multiwall bags. See note (i), page 351
Rubber hydrochloride	
Silicon dioxides*	
Soap (sodium oleate, sodium palmitate)*	
Sodium silicate*	
Sodium chloride*	
Sodium hydrosulfite*	
Sodium pentachlorophenate	Slime control agent. See note (i), page 351
Sodium phosphoaluminate*	
Sodium aluminate*	
Sodium sorbate*	
Sodium sulfate*	

Substance	Limitations
Sodium trichlorophenate	Slime control agent. See note (i), page 351
Sodium tripolyphosphate*	
Stearate-chromic chloride complex	
Sulfamic acid*	
Starch, acid modified*	
Starch, pregelatinized*	
Starch, unmodified *	
Sucrose*	
Talc*	
Titanium dioxide	See note (i), page 351
Urea*	
Urea formaldehyde polymer*	
Vanillin*	
Vinylidine chlorides (polymerized)	
Zinc hydrosulfite*	
Zinc sulfate*	
SEQUESTRANTS	
Calcium acetate	
Calcium chloride	
Calcium citrate	
Calcium diacetate	
Calcium gluconate	
Calcium hexametaphosphate	
Calcium phytate	
Citric acid	
Dipotassium phosphate	
Disodium phosphate	
Isopropyl citrate	0.02%
Monocalcium acid phosphate	
Monoisopropyl citrate	
Potassium citrate	
Sodium acid phosphate	
Sodium citrate	
Sodium diacetate	
Sodium gluconate	
Sodium hexametaphosphate	
Sodium metaphosphate	
Sodium phosphate (mono-, di-, tribasic)	
Sodium potassium tartrate	
Sodium pyrophosphate	
Sodium tartrate	
Sodium tetrapyrophosphate	
Sodium tripolyphosphate	
Sodium thiosulfate	0.1% in salt
Stearyl citrate	0.15%
Tartaric acid	
STABILIZERS	
Acacia (gum arabic)*	
Agar-agar	
Ammonium alginate*	
Calcium alginate*	
Carob bean gum (locust bean gum)	
Carrageenin	
Ghatti gum*	
Guar gum	
Potassium alginate*	
Sodium alginate*	
Sterculia gum (karaya gum)*	
Tragacanth (gum tragacanth)*	
SWEETENERS (NON-NUTRITIVE)	
Ammonium saccharin*	
Calcium cyclohexyl sulfamate	
Calcium saccharin	

Substance	Limitations
SWEETENERS (NON-NUTRITIVE) (Continued)	
Magnesium cyclohexyl sulfamate*	
Potassium cyclohexyl sulfamate*	
Saccharin	
Sodium cyclohexyl sulfamate	
Sodium saccharin	
MISCELLANEOUS	
Acetic acid	
Aluminum sodium sulfate	
Aluminum sulfate	
Ammonium bicarbonate*	
Ammonium sulfate	
Beeswax (yellow wax)*	
Beeswax, bleached (white wax)*	
Bentonite*	
Butane	
Caffeine	0.02% in cola type beverages
Calcium chloride*	
Calcium phosphate, tribasic	
Caramel	
Carbon dioxide	
Carnauba wax	
Citric acid	
Dextrans*	Average molecular weight below 100,000
Ethyl formate	0.0015% as fumigant for cashew nuts
Glutamic acid*	Salt substitute
Glutamic acid hydrochloride*	Salt substitute
Glycerin	
Glycerol monostearate	
Helium	
Hydrogen peroxide*	Bleaching agent
Lecithin*	
Magnesium carbonate	
Magnesium hydroxide	
Magnesium stearate	As migratory substance from packaging materials when used as a stabilizer.
Mannitol*	5% In special dietary foods
Methylcellulose*	See note (c), page 351
Monoammonium glutamate	
Monopotassium glutamate*	
Nitrogen	
Nitrous oxide*	Propellant for certain dairy and vegetable fat toppings in pressurized containers
Papain	
Phosphoric acid	
Potassium carbonate*	
Potassium sulfate*	
Propane	
Propylene glycol	
Rennet (rennin)*	
Silica acrogel*	See note (d), page 351
Sodium bicarbonate*	
Sodium carbonate	
Sodium carboxymethylcellulose*	See note (e), page 351
Sodium caseinate*	
Sodium pectinate*	
Sodium phosphate	
Sodium sesquicarbonate*	
Sodium tripolyphosphate	
Sorbitol	7.0% in foods for special dietary use
Torula yeast, dried*	
Triacetin (glyceryl triacetate)	

Substance	Limitations
Tricalcium phosphate	
Triethyl citrate	0.25% in egg whites

NOTES

(a) Total content of antioxidants not over 0.02% of fat or oil content, including essential (volatile) oil content of food.

(b) Not in meats or in foods recognizable as a source of vitamin B_1.

(c) U. S. P. methylcellulose, except that the methoxy content shall not be less than 27.5% and not more than 31.5% on a dry-weight basis.

(d) Finely powdered microcellular silica foam having a minimum silica content of 89.5%.

(e) Sodium salt of carboxymethylcellulose, not less than 99.5% on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2% by weight aqueous solution at 25° C.

(f) Iodine number maximum 6; and oxirane oxygen, minimum, 6.0%.

(g) Substantially free from hydrolyzable chloride and alkoxy groups, no more than 18% loss in weight after heating 4 hours at 200° C.; viscosity 300 centistokes, 600 centistokes at 25° C., specific gravity 0.96 to 0.97 at 25° C., refractive index 1.4000 to 1.404 at 25° C.

(h) Additional items listed here under other headings.

(i) Not expected to migrate under normal conditions of use.

ACQUISITIONS OF STOCK OR ASSETS—BAKERY GOODS

A baking company has been charged with illegally acquiring other bakeries in violation of Section 7 of the Clayton Act. The baking firm is charged also with directing cash payments to grocers for preferred display space, reducing prices to gain entry into grocery or retail stores, and granting discriminatory rebates, discounts and allowances in violation of Section 5 of the Federal Trade Commission Act.

The two-count complaint against the nation's largest commercial baker of white bread charged it with acquiring bakeries throughout the country and with using its increasingly dominant position to impede competitors by unlawful means. According to the complaint, the company is also one of the largest bakers of cake in the United States. Its products—sold primarily under two trade names, one for bread and another for cakes—are baked in some 86 plants in 29 states and the District of Columbia. During 1957, the company's total sales exceeded $307 million.

The baking firm purchased a baking company, of Omaha—specially named in the complaint—on November 29, 1958, for about $5.2 million, according to the complaint. The two companies had previously competed with each other in selling bread and bread-type rolls in such marketing areas as Omaha; Indianapolis; Milwaukee; and Columbus, Ohio. For example, in the Omaha area, the acquiring company had accounted for 10 per cent of the market for these products in 1957 while the acquired company had accounted for 17 per cent of the market. Through this acquisition, the complaint states, the acquiring firm has become the leading and dominant supplier in the Omaha area, as well as in other sections of the country where the acquired bakery had plants.

Since 1952, the complaint alleges, the acquiring firm has had a continuous program of purchasing bakeries, many of which were its competitors. (Issued May 5; released May 20, 1960.)—CCH TRADE REGULATION REPORTS ¶ 28,744.

WASHINGTON—Continued from page 296

Consumer Protection Aided by Industry Voluntary Actions.—During April, food manufacturers and warehousemen reported spending a total of $332,853 in 16 plant improvements, FDA reports. The improvements were made voluntarily to assure production of clean, wholesome products. Through 87 additional voluntary destruction or diversion actions, nearly 1,102 tons of unfit food products were prevented from reaching consumers.

A New York malting barley maker spent $100,000 to eliminate possible rodent and insect contamination of his products, he told Administration inspectors. He demolished an old building that was difficult to keep clean, cleared the land around his plant of debris that might attract rodents, rebuilt grain-handling equipment to provide for sanitary inspection and cleaning, and put into operation a new plant-sanitation program beginning with employee training.

A Michigan pickle firm's sanitary improvement program provided $55,000 for a new processing plant and equipment. An Illinois packer of grated cheese, onion and peppers spent $13,625 cleaning up and painting his entire building and providing such new equipment as a cog mill, a dryer, a vacuum filling machine, a stainless-steel work table and an industrial-type vacuum cleaner.

In another type of compliance action, a pharmaceutical manufacturer voluntarily destroyed labeling valued at $75,000. The labeling carried statements having the effect of misrepresentation to the public of the need for, and the value of, the firm's vitamin-mineral preparations. Drug firms, during April, voluntarily destroyed old and substandard drug products valued at $3,491.

Prosecution Cases Terminated.—Twenty-six prosecution actions were terminated during April. Seven involved unfit and misbranded foods; 19 involved illegal sales of prescription drugs and drug misbrandings. In addition, a permanent injunction was entered, for the purpose of restraining a food firm from shipping chocolate products, candy, or any other food until the plant is put in sanitary condition for the manufacture and storage of foods and until the stocks on hand are brought into compliance with the law under the supervision of FDA.

In the Public Health Service

Compounds for Treatment of Hypertension.—Public Health Service scientists reported on May 2 that a new family of compounds, decarboxylase inhibitors, is providing a promising new approach to the understanding of hypertension and may eventually offer new means of treating this puzzling disorder.

Limited clinical trials of the most effective of these compounds, alpha-methyl dopa, have been conducted by scientists of the Service's National Heart Institute, at Bethesda, Maryland, on ten hypertensive patients at the National Institutes of Health Clinical Center. The drug lowered blood pressure in all of them.

ANNOUNCING—June 6th Release of . . .

NEW THEORIES
OF FEDERAL TRADE COMMISSION ENFORCEMENT

—1960 Antitrust Law Symposium

Useful to every lawyer, needed by business—big or small—this brand-new CCH book brings the full text of the important papers delivered at the 12th Annual Meeting of the Section on Antitrust Law of the New York State Bar Association. Each of these papers—written by a top legal expert—provides a forceful discussion on major problems in the quick-changing field of antitrust law. You won't want to miss one of them!

While prime emphasis is on theories of Federal Trade Commission enforcement, some timely topics discussed include:

- ***Meeting the Impact of Antitrust Litigation in U. S. District Courts***
- ***The Department of Justice and the Congress in Antitrust***
- ***Equitable Treatment of Competitors —the Moog Directive***
- ***Reprise on Retroactivity—the Amendment to Section 11***
- ***Emerging Theories of Mergers—the Commission and Section 7***
- ***Provisions and Provisos—a Literal Legislative Lexicon***

Unequalled in scope, this handy book insures a close examination of the FTC's position on *price discrimination prohibitions, merger restrictions,* and other important statutes. Special antitrust problems in regulated industries are marked for your attention. Here is a 144-page opportunity to compare your thinking with other experts', have a personal forecast of future advancements and possible legislative changes.

ORDER YOUR COPIES TODAY!

It takes little time—hardly any bother. Just sign, detach and mail the postage-free Order Card. We'll see to it you get your copies promptly. Convenient size for desk or brief case; 6″ x 9″, heavy paper covers. Table of Contents, Topical Index, and Table of Cases for quick reference.

Price, $4 a copy.

DEPENDABLE—A Commerce Clearing House PUBLICATION

CCH PRODUCTS COMPANY
BOOKS BY MAIL
4025 W. PETERSON AVENUE, CHICAGO 46, ILLINOIS

ORDER
CARD

MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

BUSINESS REPLY MAIL
NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY—

CCH PRODUCTS COMPANY

4025 W. PETERSON AVE.

CHICAGO 46, ILL.

ORDER CARD

MAIL TODAY
for contact with helpful thinking on antitrust law.

CCH PRODUCTS COMPANY
4025 W. Peterson Ave.
Chicago 46, Ill.

Send the copies of CCH books indicated below at prices quoted. (Remittance with order saves postage and packing charge.)

Fill in Amt.

1. . . . New Theories of Federal Trade Commission Enforcement (0122). Prices: 1-4 copies, $4 ea.; 5-9, $3.70 ea.; 10-24, $3.40 ea.; 25-49, $3.20 ea.

You May Also Want:

2. . . . How to Comply with the Clayton Act, 1959 Antitrust Law Symposium (9122). Prices: 1-4 copies, $4 ea.; 5-9, $3.70 ea.; 10-24, $3.40 ea.; 25-49, $3.20 ea.

3. . . . How to Comply with the Antitrust Laws (4225). Price: $7.50 a copy.

(Subscribers for CCH's Trade Regulation Reports and Current Law Handybooks receive item 1 and should order only for extra copies.)

☐ *Remittance herewith*
☐ *Send bill*

Signature & Title .....

Firm .....

Attention .....

Street Address .....

0122—381

City, Zone & State .....

(If ordering by letter or purchase order, please attach this card.)

A COMMERCE CLEARING HOUSE PUBLICATION